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

FARM CREDIT ADMINISTRATION

12 CFR Parts 602, 618, and 621

RIN 3052–AC76

Releasing Information; General Provisions; Accounting and Reporting Requirements; Reports of Accounts and Exposures

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA or we) adopted a final rule to establish a regulatory framework for the reliable, timely, accurate, and complete reporting of Farm Credit System (System) accounts and exposures for examination activities and risk evaluation. The final rule specifies the reporting requirements and performance responsibilities, including, but not limited to, establishing uniform and standard data fields to be collected from all System institutions and a disciplined and secure delivery of information. The final rule authorizes a Reporting Entity (defined as the Federal Farm Credit Banks Funding Corporation or an entity approved by FCA), to collect data from all banks and associations and serve as the central data repository manager. Additionally, the final rule requires all banks and associations to provide data to the Reporting Entity to facilitate the collection, enhancement, and reporting of data to FCA. In accordance with the law, the effective date of the rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session.

DATES:

Effective date: Under the authority of 12 U.S.C. 2252, the regulation amending 12 CFR parts 602, 618, and 621 published on December 24, 2013 (78 FR 77557), is effective February 21, 2014.

Compliance Date: All provisions of this regulation require compliance on the effective date, except the Reporting Entity's requirements under § 621.15(b)(1) through (6). We are delaying compliance with these requirements to allow for the development of and transition to the System's central data repository. We will publish the compliance date for these requirements in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Susan Coleman, Senior Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4491, TTY (703) 883–4056, or

Jane Virga, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: The Farm Credit Administration (FCA or we) adopted a final rule to establish a regulatory framework for the reliable, timely, accurate, and complete reporting of Farm Credit System (System) accounts and exposures for examination activities and risk evaluation. The final rule specifies the reporting requirements and performance responsibilities, including, but not limited to, establishing uniform and standard data fields to be collected from all System institutions and a disciplined and secure delivery of information. The final rule authorizes a Reporting Entity (defined as the Federal Farm Credit Banks Funding Corporation or an entity approved by FCA), to collect data from all banks and associations and serve as the central data repository manager. Additionally, the final rule requires all banks and associations to provide data to the Reporting Entity to facilitate the collection, enhancement, and reporting of data to FCA. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is February 21, 2014.

(12 U.S.C. 2252(a)(9) and (10))

Dated: February 21, 2014.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2014–04197 Filed 2–25–14; 8:45 am]

BILLING CODE 6705–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2013–0041]

RIN 0960–AH61

Extension of Expiration Dates for Several Body System Listings

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are extending the expiration dates of the following body systems in the Listing of Impairments (listings) in our regulations: Growth Impairment, Musculoskeletal System, Respiratory System, Cardiovascular System, Digestive System, Skin Disorders, and Neurological. We are making no other revisions to these body systems in this final rule. This extension will ensure that we continue to have the criteria we need to evaluate impairments in the affected body systems at step three of the sequential evaluation processes for initial claims and continuing disability reviews.

DATES: This final rule is effective on February 26, 2014.

FOR FURTHER INFORMATION CONTACT:

Cheryl A. Williams, Director, Office of Medical Policy, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Background

We use the listings in appendix 1 to subpart P of part 404 of 20 CFR at the third step of the sequential evaluation process to evaluate claims filed by adults and children for benefits based on disability under the title II and title XVI programs.[1] 20 CFR 404.1520(d), 416.920(d). The listings are in two parts: Part A has listings criteria for adults and Part B has listings criteria for children. If you are age 18 or over, we apply the listings criteria in part A when we assess your impairment or combination of impairments. If you are under age 18,

[1] We also use the listings in the sequential evaluation processes we use to determine whether a beneficiary's disability continues. See 20 CFR 404.1594, 416.994, and 416.994a.

we first use the criteria in part B of the listings when we assess your impairment(s). If the criteria in part B do not apply, we may use the criteria in part A when those criteria give appropriate consideration to the effects of your impairment(s). 20 CFR 404.1525(b), 416.925(b).

Explanation of Changes

In this final rule, we are extending the dates on which the listings for seven body systems will no longer be effective as set out in the following chart:

Listing	Current expiration date	Extended expiration date
Growth Impairment 100.00	July 1, 2014	January 30, 2015.
Musculoskeletal System (1.00 and 101.00)	July 1, 2014	July 31, 2015.
Respiratory System (3.00 and 103.00)	April 1, 2014	January 30, 2015.
Cardiovascular System (4.00 and 104.00)	October 1, 2014	July 31, 2015.
Digestive System (5.00 and 105.00)	April 1, 2014	January 30, 2015.
Skin Disorders 8.00 and 108.00	April 1, 2014	January 30, 2015.
Neurological 11.00 and 111.00	April 1, 2014	July 31, 2015.

We continue to revise and update all of the listings on a regular basis, including those body systems not affected by this final rule.[2] We intend to update the seven listings affected by this final rule as quickly as possible, but may not be able to publish final rules revising these listings by the current expiration dates. Therefore, we are extending the expiration dates listed above.

Regulatory Procedures

Justification for Final Rule

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in promulgating regulations. Section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5). Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final regulation. The APA provides exceptions to the notice-and-comment requirements when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest.

We determined that good cause exists for dispensing with the notice and public comment procedures. 5 U.S.C. 553(b)(B). This final rule only extends the date on which several body system listings will no longer be effective. It makes no substantive changes to our rules. Our current regulations[3] provide that we may extend, revise, or promulgate the body system listings again. Therefore, we have determined that opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes to the listings in these body systems. Without an extension of the expiration dates for these listings, we will not have the criteria we need to assess medical impairments in these body systems at step three of the sequential evaluation processes. We therefore find it is in the public interest to make this final rule effective on the publication date.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it. We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule does not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This rule does not create any new or affect any existing collections, and therefore does not require OMB approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: February 18, 2014.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending appendix 1 to subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–b) and (d)–(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 by revising items 1, 2, 4, 5, 6, 9, and 12 of the introductory text before Part A to read as follows:

[2] Since we extended the expiration date of some of these listings in June 2012 (77 FR 35264 (2012)), we published final rules revising congenital disorders that affect multiple body systems (78 FR 7659 (2013)), and the revised medical criteria for evaluating visual disorders in the special senses and speech body system (78 FR 18837 (2013)). We also published proposed rules for revised medical criteria for evaluating respiratory system disorders (78 FR 7968 (2013)), revised medical criteria for evaluating genitourinary disorders (78 FR 7695 (2013)), revised listings for growth disorders and weight loss in children (78 FR 30249 (2013)), revised medical criteria for evaluating hematological disorders (78 FR 69324 (2013)), and revised medical criteria for evaluating cancer (78 FR 76508 (2013)). We also have published an advance notice of proposed rulemaking requesting comments on whether and how we should revise the listing criteria for evaluating hearing loss and disturbances of labyrinthine-vestibular function in adults and children (78 FR 53700 (2013)).

[3] See the first sentence of appendix 1 to 20 CFR part 404, subpart P.

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

1. Growth Impairment (100.00): January 30, 2015.

2. Musculoskeletal System (1.00 and 101.00): July 31, 2015.

* * * * *

4. Respiratory System (3.00 and 103.00): January 30, 2015.

5. Cardiovascular System (4.00 and 104.00): July 31, 2015.

6. Digestive System (5.00 and 105.00): January 30, 2015

* * * * *

9. Skin Disorders (8.00 and 108.00): January 30, 2015.

* * * * *

12. Neurological (11.00 and 111.00): July 31, 2015.

* * * * *

[FR Doc. 2014–04123 Filed 2–25–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9659]

RIN 1545–BJ15

Property Transferred in Connection With the Performance of Services Under Section 83

AGENCY: Internal Revenue Service, Department of the Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to property transferred in connection with the performance of services under section 83 of the Internal Revenue Code (Code). These final regulations affect certain taxpayers who receive property transferred in connection with the performance of services.

DATES:

Effective Date: These regulations are effective on February 26, 2014.

Applicability Date: For dates of applicability, see § 1.83–3(l).

FOR FURTHER INFORMATION CONTACT: Thomas Scholz or Michael Hughes at (202) 317–5600 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On May 30, 2012, the Department of Treasury (Treasury) and the Internal Revenue Service (IRS) published a notice of proposed rulemaking (REG–141075–09) in the **Federal Register** (77 FR 31783) under section 83 of the Code. Treasury and the IRS received two comments responding to the notice of proposed rulemaking. No public hearing was requested and no public hearing was held. After consideration of these comments, Treasury and the IRS adopt the proposed regulations as final regulations with the modifications described in this preamble.

Explanation of Provisions

Section 83 of the Code addresses the tax consequences of the transfer of property in connection with the performance of services. These final regulations provide several clarifications regarding whether a substantial risk of forfeiture exists in connection with property subject to section 83. Specifically, the final regulations clarify that (1) except as specifically provided in section 83(c)(3) and §§ 1.83–3(j) and (k), a substantial risk of forfeiture may be established *only* through a service condition or a condition related to the purpose of the transfer, (2) in determining whether a substantial risk of forfeiture exists based on a condition related to the purpose of the transfer, both the likelihood that the forfeiture event will occur and the likelihood that the forfeiture will be enforced must be considered, and (3) except as specifically provided in section 83(c)(3) and §§ 1.83–3(j) and (k), transfer restrictions do not create a substantial risk of forfeiture, including transfer restrictions that carry the potential for forfeiture or disgorgement of some or all of the property, or other penalties, if the restriction is violated.

Summary of Comments

Treasury and the IRS received two written comments on the notice of proposed rulemaking. The first comment was not responsive to the notice of proposed rulemaking. The second comment expressed concern that the proposed regulations result in a narrowing of the circumstances that would establish a substantial risk of forfeiture and requested clarification regarding whether an involuntary separation from service without cause could establish a substantial risk of forfeiture. The comment noted that, for purposes of section 409A, an amount that is payable only upon a service provider's involuntary separation from service without cause is subject to a substantial risk of forfeiture if the possibility of forfeiture is substantial, and it suggested that these regulations specifically state that an involuntary separation without cause may qualify as a substantial risk of forfeiture under section 83 in appropriate circumstances.

These regulations are intended to clarify the definition of a substantial risk of forfeiture and are consistent with the interpretation that the IRS historically has applied, and therefore from the perspective of Treasury and the IRS they do not constitute a narrowing of the requirements to establish a substantial risk of forfeiture. See *Robinson* v. *Commissioner,* 805 F.2d 38 (1st Cir. 1986). Further, Treasury and the IRS believe that these regulations should not be modified to state that an involuntary separation from service without cause may qualify as a substantial risk of forfeiture under section 83. While a service provider's right to receive property (or an amount in cash) in the future upon the service provider's involuntary separation from service without cause may be subject to a substantial risk of forfeiture for purposes of section 409A if the possibility of forfeiture is substantial, a substantial risk of forfeiture under section 83 can exist only when property is actually transferred in connection with the performance of services. A right to receive property in the future is generally not property for purposes of section 83. See § 1.83–3(e). Accordingly, an involuntary separation from service without cause cannot qualify as a substantial risk of forfeiture under section 83 if property is not transferred until after the separation from service occurs.

When a transfer of property does occur, a substantial risk of forfeiture may be established through a substantial services condition or a condition related to the purpose of the transfer if the possibility of forfeiture is substantial. The acceleration of vesting upon an involuntary separation from service without cause (or separation from service as a result of death or disability) will not cause a requirement of substantial services that otherwise would be treated as a substantial risk of forfeiture to fail to qualify as a substantial risk of forfeiture, provided that facts and circumstances do not demonstrate that the occurrence of an involuntary separation from service without cause is likely to occur during the agreed upon service period.

Certain practitioners informally requested clarification regarding the application of section 83(c)(3) to a variation of the facts set forth in Example 4 of proposed regulation § 1.83–3(j)(2). Specifically, practitioners asked whether the purchase of shares in a transaction not exempt from section 16(b) of the Securities Exchange Act of 1934 prior to the exercise of a stock option that would not otherwise give rise to section 16(b) liability would defer taxation of the stock option exercise. Treasury and the IRS do not

believe that such a non-exempt purchase of shares would defer taxation of the subsequent stock option exercise. This result is consistent with Example 3 of § 1.83–3(j)(2). In response to these requests for clarification, Treasury and the IRS have revised *Example 4* of proposed regulation § 1.83–3(j)(2) to address the situation raised.

Applicability Date

These regulations apply to property transferred on or after January 1, 2013.

Effect on Other Documents

Rev. Rul. 2005–48 (2005–2 CB 259) is obsolete as of February 26, 2014.

Special Analyses

It has been determined that this final regulation is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13653. Therefore, a regulatory 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 rule making preceding these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal authors of these final regulations are Thomas Scholz and Michael Hughes, Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). Other personnel from Treasury and the IRS also 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 continues to read in part as follows:

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

■ **Par. 2.** Section 1.83–3 is amended by:

■ 1. Revising paragraph (c)(1).

■ 2. Adding *Example 6* and *Example 7* to paragraph (c)(4).

■ 3. Adding *Example 4* to paragraph (j)(2).

■ 4. Removing paragraph (j)(3).

■ 5. Removing paragraph (k).

■ 6. Redesignating paragraph (k)(1) as paragraph (k).

■ 7. Adding paragraph (l).

The revisions and additions read as follows:

§ 1.83–3 Meaning and use of certain terms.

* * * * *

(c) *Substantial risk of forfeiture.* (1) *In general.* For purposes of section 83 and these regulations, whether a risk of forfeiture is substantial or not depends upon the facts and circumstances. Except as set forth in paragraphs (j) and (k) of this section, a substantial risk of forfeiture exists only if rights in property that are transferred are conditioned, directly or indirectly, upon the future performance (or refraining from performance) of substantial services by any person, or upon the occurrence of a condition related to a purpose of the transfer if the possibility of forfeiture is substantial. Property is not transferred subject to a substantial risk of forfeiture if at the time of transfer the facts and circumstances demonstrate that the forfeiture condition is unlikely to be enforced. Further, property is not transferred subject to a substantial risk of forfeiture to the extent that the employer is required to pay the fair market value of a portion of such property to the employee upon the return of such property. The risk that the value of property will decline during a certain period of time does not constitute a substantial risk of forfeiture. A nonlapse restriction, standing by itself, will not result in a substantial risk of forfeiture. A restriction on the transfer of property, whether contractual or by operation of applicable law, will result in a substantial risk of forfeiture only if and to the extent that the restriction is described in paragraph (j) or (k) of this section. For this purpose, transfer restrictions that will not result in a substantial risk of forfeiture include, but are not limited to, restrictions that if violated, whether by transfer or attempted transfer of the property, would result in the forfeiture of some or all of the property, or liability by the employee for any damages, penalties, fees, or other amount.

* * * * *

(4) * * *

Example 6. On April 3, 2013, Y corporation grants to Q, an officer of Y, a nonstatutory option to purchase Y common stock. Although the option is immediately exercisable, it has no readily ascertainable fair market value when it is granted. Under the option, Q has the right to purchase 100 shares of Y common stock for $10 per share, which is the fair market value of a Y share on the date of grant of the option. On August 1, 2013, Y sells its common stock in an initial public offering. Pursuant to an underwriting agreement entered into in connection with the initial public offering, Q agrees not to sell, otherwise dispose of, or hedge any Y common stock from August 1 through February 1 of 2014 (''the lock-up period''). Q exercises the option and Y shares are transferred to Q on November 15, 2013, during the lock-up period. The underwriting agreement does not impose a substantial risk of forfeiture on the Y shares acquired by Q because the provisions of the agreement do not condition Q's rights in the shares upon anyone's future performance (or refraining from performance) of substantial services or on the occurrence of a condition related to the purpose of the transfer of shares to Q. Accordingly, neither section 83(c)(3) nor the imposition of the lock-up period by the underwriting agreement precludes taxation under section 83 when the shares resulting from exercise of the option are transferred to Q.

Example 7. Assume the same facts as in *Example 6,* except that on August 1, 2013, Y also adopts an insider trading compliance program, under which, as applied to 2013, insiders (such as Q) may trade Y shares only during a limited number of days following each quarterly earnings release (''a trading window''). Under the program, if Q trades Y shares outside a trading window without Y's permission, Y has the right to terminate Q's employment. However, the exercise of the nonstatutory options outside a trading window for Y shares is not prohibited under the insider trading compliance program. Q fully exercises the option, and Y shares are transferred to Q, on November 15, 2013. The exercise of the option occurs outside a trading window, and, on the date of exercise, Q is in possession of material nonpublic information concerning Y that would subject him to liability under Rule 10b–5 under the Securities Exchange Act of 1934 if Q sold the Y shares while in possession of such information. Neither the insider trading compliance program nor the potential liability under Rule 10b–5 impose a substantial risk of forfeiture on the Y shares acquired by Q because the provisions of the program and Rule 10b–5 do not condition Q's rights in the shares upon anyone's future performance (or refraining from performance) of substantial services or on the occurrence of a condition related to the purpose of the transfer of shares to Q. Accordingly, none of section 83(c)(3), the imposition of the trading windows by the insider trading compliance program, and the potential liability under Rule 10b–5 preclude taxation under section 83 when the shares resulting from exercise of the option are transferred to Q.

* * * * *

(j) * * *

(2) * * *

Example 4. (i) On June 3, 2013, Y corporation grants to Q, an officer of Y, a nonstatutory option to purchase Y common

stock. Y stock is traded on an established securities market. Although the option is immediately exercisable, it has no readily ascertainable fair market value when it is granted. Under the option, Q has the right to purchase 100 shares of Y common stock for $10 per share, which is the fair market value of a Y share on the date of grant of the option. The grant of the option is not one that satisfies the requirements for a transaction that is exempt from section 16(b) of the Securities Exchange Act of 1934. On December 15, 2013, Y stock is trading at more than $10 per share. On that date, Q fully exercises the option, paying the exercise price in cash, and receives 100 Y shares. Q's rights in the shares received as a result of the exercise are not conditioned upon the future performance of substantial services. Because no exemption from section 16(b) was available for the June 3, 2013 grant of the option, the section 16(b) liability period expires on December 1, 2013. Accordingly, the section 16(b) liability period expires *before* the date that Q exercises the option and the Y common stock is transferred to Q. Thus, the shares acquired by Q pursuant to the exercise of the option are not subject to a substantial risk of forfeiture under section 83(c)(3) as a result of section 16(b). As a result, section 83(c)(3) does not preclude taxation under section 83 when the shares acquired pursuant to the December 15, 2013 exercise of the option are transferred to Q.

(ii) Assume the same facts as in paragraph (i) of this *Example 4* except that Q exercises the nonstatutory option on October 30, 2013 when Y stock is trading at more than $10 per share. The shares acquired are subject to a substantial risk of forfeiture under section 83(c)(3) as a result of section 16(b) through December 1, 2013.

(iii) Assume the same facts as in paragraph (i) of this *Example 4* except that on November 5, 2013, Q also purchases 100 shares of Y common stock on the public market. The purchase of the shares is not a transaction exempt from section 16(b) of the Securities Exchange Act of 1934. Because no exemption from section 16(b) was available for the November 5, 2013 purchase of shares, the section 16(b) liability period with respect to such shares will last for a period of six months after the November 5, 2013 purchase of shares. Notwithstanding the non-exempt purchase of Y common stock on November 5, 2013, the shares acquired by Q pursuant to the December 15, 2013 exercise of the option are not subject to a substantial risk of forfeiture under section 83(c)(3) as a result of section 16(b). As a result, section 83(c)(3) does not preclude taxation under section 83 when the shares acquired pursuant to the December 15, 2013 exercise of the option are transferred to Q.

* * * * *

(l) *Effective/applicability date.* This section applies to property transferred on or after January 1, 2013. For rules relating to property transferred before that date, see § 1.83–3 as contained in 26 CFR part 1 (as of April 1, 2012).

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: January 31, 2014.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2014–03988 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2008–0878; FRL–9906–89–OW]

National Primary Drinking Water Regulations: Minor Corrections to the Revisions to the Total Coliform Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is making minor corrections to the final Revisions to the Total Coliform Rule (RTCR), as authorized under the Safe Drinking Water Act, to correct typographical errors in sections relating to recordkeeping and State primacy requirements, which could affect implementation and enforcement of the RTCR if they were left uncorrected. This action also includes other edits to the final rule language that are intended to improve the understanding of the rule and avoid confusion. This action does not impose new requirements; rather it clarifies what must be included in States' primacy applications related to this rule and the specific records water systems must keep.

DATES: This rule is effective on April 28, 2014 without further notice, unless EPA receives adverse comment by March 28, 2014. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. The incorporation by reference of certain material listed in the rule was approved by the Director of the Federal Register as of April 15, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2008–0878, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–OW–2008–0878.
- *Hand Delivery:* EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2008–0878. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Water Docket, EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301

Constitution Ave. NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 202–566–2426.

FOR FURTHER INFORMATION CONTACT: Sean Conley, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC–4607M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–1781; email address: *conley.sean@epa.gov*. For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 10 a.m. to 4 p.m. Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Why is EPA using a direct final rule?

EPA is publishing this direct final rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment; this action only corrects typographical errors and makes clarifying edits and does not impose new requirements. However, in the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate document that will serve as the proposed rule to make the corrections and clarifying edits to the RTCR if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Comments should be submitted only for the corrections being made in this direct final rule, not for other aspects of the final RTCR. For further information about commenting on this rule, see the **ADDRESSES** section of this document.

If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We would address all public comments in any subsequent final rule based on the proposed rule.

B. Regulated Categories and Entities

Entities potentially regulated by the RTCR as corrected are all public water systems (PWSs). Regulated categories and entities include the following:

Category	Examples of regulated entities
Industry	Privately-owned community water systems (CWSs), transient non-community water systems (TNCWSs), and non-transient non-community water systems (NTNCWSs).
Federal, State, Tribal, and local governments.	Publicly-owned CWSs, TNCWSs, and NTNCWSs.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities regulated by this action. This table lists the types of entities that EPA is now aware of that could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of ''public water system'' in § 141.2 and the section entitled ''Coverage'' in § 141.3 in title 40 of the Code of Federal Regulations (CFR), and the applicability criteria in § 141.851(b) of the final RTCR. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

C. Copies of This Document and Other Related Information

This document is available for download at *http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/regulation_revisions.cfm*. For other related information, see preceding discussion on docket.

D. Minor Corrections to the Revisions to the Total Coliform Rule (RTCR)

A. Today's final rule corrects, as authorized under the Safe Drinking Water Act (SDWA), two typographical errors in the final RTCR (78 FR 10269, February 13, 2013) rule language. First, this action corrects a mistaken cross-reference regarding water system recordkeeping requirements for assessment forms and documentation of corrective actions and sanitary defects. EPA is correcting the cross-reference at § 141.861(b)(1) to correctly provide that assessments, corrective actions and identification of sanitary defects are required under the treatment technique requirements of § 141.859 of the final RTCR. The burden for these recordkeeping requirements was reflected in the Revised Total Coliform Rule (see Paperwork Reduction Act, section II.B of this notice) and in section 7 of the Economic Analysis (EA) for the Revised Total Coliform Rule (EPA–815–R–12–004). EPA also discussed these requirements in the preamble to the final RTCR on page 10295. Second, today's final rule also corrects the introductory paragraph at § 142.16(q)(2) to correctly indicate that the State's application for primacy must contain a written description of all provisions included in the subsections of the paragraph, (q)(2)(i) through (q)(2)(ix). It was always EPA's intent that primacy applications must contain a written description of all provisions in § 142.16(q)(2), but when EPA added subparagraph (q)(2)(ix) to the final rule, EPA neglected to change the numbering in the paragraph (2) lead-in to the list of elements. EPA intended this to be the case, as demonstrated in the preamble to the final RTCR on page 10301. In addition, the burden for this State activity was also included in section 7 of the EA for the RTCR. EPA is not developing a new EA for today's action because the EA for the final RTCR accounts for all costs associated with this rule.

Today's final rule also corrects the numbering in § 141.855(a) by adding subparagraph (d)(2) and reserving it, to most simply correct a numbering error that identified a subparagraph (d)(1) without a subsequent (d)(2). Correcting the numbering in this fashion will not interfere with any cross references to this subparagraph.

Today's rule also includes clarifying revisions to the language regarding primacy applications in § 142.16(q)(2)(ii) to make it more clear in the special primacy requirements section of the rule that systems must implement at least one of listed additional criteria to qualify for reduced monitoring. EPA clearly intended this to be the case, as reflected in § 141.854(h)(2) for NCWSs and § 141.855(d) for CWSs, and in the preamble to the final rule at page 10281 and 10282.

Next, the final rule clarifies the situations requiring public notification in Appendix A to Subpart Q of Part 141 to list out all of the possible reporting violations under the RTCR that will require Tier 3 public notice. EPA clearly intended this to be the case, as reflected in item (6) in Table 1 to § 141.204 (Violation Categories and Other Situations Requiring a Tier 3 Public

Notice), which provides that all reporting and recordkeeping violations under the RTCR require Tier 3 public notice. Also, page 10294 of the preamble to the final RTCR clearly states that Tier 3 PN is required for both monitoring and reporting violations under the RTCR.

Finally, the final rule clarifies the analytical methods table at § 141.852(a)(5) to place the citation ''Standard Methods Online 9223 B–97'' for the Colilert analytical method in the correct column.

These revisions do not change any rule requirements, are consistent with the rule requirements as intended by the Total Coliform Rule/Distribution System Advisory Committee that recommended the revisions to the Total Coliform Rule, and are intended only to clarify requirements and reduce confusion.

II. Statutory and Executive Order Review

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

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. In this action, EPA is making minor corrections to the final RTCR to correct typographical errors in sections relating to recordkeeping and State primacy requirements and other edits to the final rule language that are intended to improve the understanding of the rule and avoid confusion. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations (40 CFR Parts 141 and 142) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2040–0205. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any ''not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' However, the RFA also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment (5 U.S.C. 601(3)–(5)). In addition, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of the RTCR on small entities, EPA considered small entities to be PWSs serving 10,000 or fewer people. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act (SDWA) for small system flexibility provisions. As required by the RFA, EPA proposed using this alternative definition in the FR (63 FR 7620, February 13, 1998), requested public comment, consulted with the SBA, and finalized the alternative definition in the agency's Consumer Confidence Report regulation (63 FR 44524, August 19, 1998). As stated in that Final Rule, the alternative definition would be applied for all future drinking water regulations.

After considering the economic impacts of the minor corrections to the RTCR on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The costs for recordkeeping and State primacy requirements were accounted for and detailed in the RTCR EA and summarized in the preamble of the final RTCR. A copy of the final RTCR and the RTCR EA can be found at *http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/regulation_revisions.cfm*.

D. Unfunded Mandates Reform Act (UMRA)

This rule does not contain a Federal mandate under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538. This rule makes minor editorial corrections and clarifying edits to the final RTCR. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it makes only minor corrections and clarifying edits that will not significantly or uniquely affect small governments.

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 as specified in Executive Order 13132. Today's action makes minor corrections to the final RTCR to correct typographical errors in sections relating to recordkeeping and State primacy requirements and other edits to the final rule language that are intended to improve the understanding of the rule and avoid confusion. The recordkeeping and primacy requirements as corrected by today's action were included in the cost calculations that were described in the preamble to the final RTCR and used to determine that Executive Order 13132 does not apply to the final RTCR.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rule makes minor corrections to the final RTCR that will not have tribal implications. 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 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

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

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant

regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable voluntary consensus standards.

This final rule makes only minor corrections and edits that do not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission. Agencies must do this by identifying and addressing, as appropriate, any disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This rule makes minor corrections and edits to the final RTCR that will not have disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

K. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with section 1412(d) and (e) of SDWA, EPA consulted with the Science Advisory Board (SAB), National Drinking Water Advisory Council (NDWAC), and the Secretary of the U.S. Department of Health and Human Services on the final RTCR. Because today's action is making only minor corrections to the final RTCR to correct typographical errors and other edits to the final rule language that are intended to improve the understanding of the rule and avoid confusion, EPA did not consult with the SAB, NDWAC or the Secretary on today's action.

L. Considerations of Impacts on Sensitive Subpopulations as Required by Section 1412(b)(3)(C)(i)(V) of the 1996 Amendments of SDWA

As required by Section 1412(b)(3)(C)(i)(V) of SDWA, EPA sought public comment regarding the effects of contamination associated with the proposed RTCR on the general population and sensitive subpopulations. Sensitive subpopulations include ''infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population'' (SDWA section 1412(b)(3)(C)(i)(V), 42 U.S.C. 300g–1(b)(3)(C)(i)(V)). As indicated in the preamble to the final RTCR, EPA anticipates that the requirements of the final RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing exposure and risk from these contaminants in drinking water to the entire general population.

Today's final rule is making only minor corrections to the final RTCR to correct typographical errors and other edits to the final rule language that are intended to improve the understanding of RTCR and avoid confusion and does not alter the conclusion that the final RTCR seeks to provide a similar level of drinking water protection to all groups including sensitive subpopulations.

M. Effect of Compliance With the Minor Corrections to the RTCR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA, as amended, requires that, in promulgating an NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial and financial (TMF) capacity of PWSs. EPA completed an analysis of the impact of complying with the requirements of the RTCR on the TMF capacity of PWSs and a detailed discussion of EPA's analysis was presented in chapter 8.14 of the RTCR EA. The PWS recordkeeping requirements as corrected by today's rule were included in the analysis of the TMF capacity for the final RTCR and therefore no changes to that analysis are needed to accompany this action.

N. Congressional Review Act

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 (U.S.). EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the U.S. 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). This rule will be effective April 28, 2014.

List of Subjects

40 CFR Part 141

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indian-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: February 10, 2014.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, Title 40 chapter 1 of the Code of Federal Regulations is amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 2. Appendix A to Subpart Q of Part 141 is amended by revising entries I.A.1 and I.A.2 to read as follows:

Appendix A to Subpart Q of Part 141—NPDWR Violations and Other Situations Requiring Public Notice [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring, testing & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of National Primary Drinking Water Regulations (NPDWR): [3]				
A. Microbiological Contaminants				
1.a Total coliform bacteria †	2	141.63(a)	3	141.21(a)–(e).
1.b Total coliform (TT violations resulting from failure to perform assessments or corrective actions, monitoring violations, and reporting violations) ‡.	2	141.860(b)(1)	3	141.860(c)(1).
				141.860(d)(1).
1.c Seasonal system failure to follow State-approved start-up plan prior to serving water to the public or failure to provide certification to State ‡.	2	141.860(b)(2)	3	141.860(d)(3).
2.a Fecal coliform/*E. coli* †	1	141.63(b)	[4] 1,3	141.21(e)
2.b *E. coli* (MCL, monitoring, and reporting violations) ‡	1	141.860 (a)	3	141.860(c)(2)
				141.860(d)(1).
				141.860(d)(2).
2.c *E. coli* (TT violations resulting from failure to perform level 2 Assessments or corrective action) ‡.	2	141.860(b)(1)		
* * * *	*		*	*

Appendix A—Endnotes

† Until March 31, 2016.

‡ Beginning April 1, 2016.

1. Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under §§ 141.202(a) and 141.203(a).

2. MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

3. The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

4. Failure to test for fecal coliform or E. coli is a Tier 1 violation if testing is not done after any repeat sample tests positive for coliform. All other total coliform monitoring and testing procedure violations are Tier 3.

* * * * *

■ 3. Section 141.852 is amended by revising the entry for ''Total Coliforms'' in the table in paragraph (a)(5) to read as follows:

§ 141.852 Analytical methods and laboratory certification.

(a) * * *

(5) * * *

Organism	Methodology category	Method [1]	Citation [1]
Total coliforms	Lactose Fermentation Methods.	Standard Total Coliform Fermentation Technique	Standard Methods 9221 B.1, B.2 (20th ed.; 21st ed.).[2 3]
			Standard Methods Online 9221 B.1, B.2–99.[2 3]
		Presence-Absence (P–A) Coliform Test	Standard Methods 9221 D.1, D.2 (20th ed.; 21st ed.).[2 7]
			Standard Methods Online 9221 D.1, D.2–99.[2 7]
	Membrane Filtration Methods.	Standard Total Coliform Membrane Filter Procedure.	Standard Methods 9222 B, C (20th ed.; 21st ed.).[2 4]
			Standard Methods Online 9222 B–97[2 4], 9222 C–97.[2 4]
		Membrane Filtration using MI medium	EPA Method 1604.[2]
		m-ColiBlue24® Test [2 4]	
		Chromocult [2 4]	
	Enzyme Substrate Methods.	Colilert®	Standard Methods 9223 B (20th ed.; 21st ed.).[2 5]
			Standard Methods Online 9223 B–97.[2 5]
		Colisure®	Standard Methods 9223 B (20th ed.; 21st ed.).[2 5 6]
			Standard Methods Online 9223 B–97.[2 5 6]

Organism	Methodology category	Method [1]	Citation [1]
Total coliforms			
	.....	E*Colite® Test [2]	
	.....	Readycult® Test [2]	
	.....	modified Colitag® Test [2]	
* * * * * * *			

[1] The procedures must be done in accordance with the documents listed in paragraph (c) of this section. For Standard Methods, either editions, 20th (1998) or 21st (2005), may be used. For the Standard Methods Online, the year in which each method was approved by the Standard Methods Committee is designated by the last two digits following the hyphen in the method number. The methods listed are the only online versions that may be used. For vendor methods, the date of the method listed in paragraph (c) of this section is the date/version of the approved method. The methods listed are the only versions that may be used for compliance with this rule. Laboratories should be careful to use only the approved versions of the methods, as product package inserts may not be the same as the approved versions of the methods.

[2] Incorporated by reference. See paragraph (c) of this section.

[3] Lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between lactose broth and lauryl tryptose broth using the water normally tested, and if the findings from this comparison demonstrate that the false-positive rate and false-negative rate for total coliforms, using lactose broth, is less than 10 percent.

[4] All filtration series must begin with membrane filtration equipment that has been sterilized by autoclaving. Exposure of filtration equipment to UV light is not adequate to ensure sterilization. Subsequent to the initial autoclaving, exposure of the filtration equipment to UV light may be used to sanitize the funnels between filtrations within a filtration series. Alternatively, membrane filtration equipment that is pre-sterilized by the manufacturer (i.e., disposable funnel units) may be used.

[5] Multiple-tube and multi-well enumerative formats for this method are approved for use in presence-absence determination under this regulation.

[6] Colisure® results may be read after an incubation time of 24 hours.

[7] A multiple tube enumerative format, as described in *Standard Methods for the Examination of Water and Wastewater* 9221, is approved for this method for use in presence-absence determination under this regulation.

* * * * *

§ 141.855 [Amended]

■ 4. Section 141.855 is amended by adding a reserved paragraph (d)(2).

§ 141.861 [Amended]

■ 5. In § 141.861, paragraph (b)(1) is amended by removing ''§ 141.858'' and adding in its place ''§ 141.859''.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 6. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 7. Section 142.16 is amended by revising paragraphs (q)(2) introductory text and (q)(2)(ii) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(q) * * *

(2) The State's application for primacy for subpart Y must include a written description for each provision included in paragraphs (q)(2)(i) through (ix) of this section.

* * * * *

(ii) Reduced Monitoring Criteria—An indication of whether the State will adopt the reduced monitoring provisions of 40 CFR part 141, subpart Y. If the State adopts the reduced monitoring provisions, it must describe the specific types or categories of water systems that will be covered by reduced monitoring and whether the State will use all or a reduced set of the criteria specified in §§ 141.854(h)(2) and 141.855(d)(1)(iii) of this chapter. For each of the reduced monitoring criteria, the State must describe how the criterion will be evaluated to determine when systems qualify.

* * * * *

[FR Doc. 2014–04173 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0638; FRL–9906–70]

Fluxapyroxad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluxapyroxad in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 26, 2014. Objections and requests for hearings must be received on or before April 28, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0638, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: [(703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather

provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. If OCSPP test guidelines are cited, insert the following: To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0638 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 28, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0638, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 19, 2012 (77 FR 75082) (FRL–9372–6), January 16, 2013 (78 FR 3377) (FRL–9375–4), and July 19, 2013 (78 FR 43115) (FRL–9392–9), EPA issued notices pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F8053, PP 2F8058 and PP 3F8161 by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petitions requested that 40 CFR 180.666 be amended by establishing tolerances for residues of the fungicide fluxapyroxad, 3-(difluoromethyl)-1-methyl-N-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide, in or on almond at 0.05 parts per million (ppm); almond, hulls at 4.0 ppm; berry, low growing, subgroup 13–07G at 4.0 ppm; bushberry, subgroup 13–07B at 6.0 ppm; caneberry, subgroup 13–07A at 6.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm; grapes at 2.0 ppm; grapes, raisin at 5.7 ppm; pecans at 0.05 ppm; rice, bran at 8.5 ppm; rice, grain at 5.0 ppm; rice, hulls strawberry at 4.0 ppm; sugarcane, cane at 3.0 ppm; vegetable, *brassica* leafy, group 5 at 3.0 ppm; vegetable, bulb, group 3–07 at 0.8 ppm; vegetable, cucurbit, group 9 at 0.4 ppm; vegetable, leafy, except *brassica,* group 4 at 15.0 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.7 ppm (PP 2F8053); nongrass animal feeds, group 18 at 0.5 ppm; mint at 0.05 ppm (PP 2F8058); and by amending the tolerance for fruit, stone, group 12 from 2.0 ppm to 3.0 ppm (PP 3F8161). The documents referenced summaries of the petitions prepared by BASF Corporation, the registrant, which are available in dockets EPA–HQ–OPP–2012–0638 (PP 2F8053), EPA–HQ–OPP–2012–0924 (PP 2F8058), and EPA–HQ–OPP–2013–0477 (PP 3F8161), *http://www.regulations.gov*.

Based on EPA's review of the data supporting the petitions, BASF Corporation revised their petition PP 2F8053 by proposing tolerances for fish-freshwater finfish; fish-shelfish, crustacean; and hog, meat byproducts; and by decreasing, increasing, or deleting previously proposed tolerances for various commodities, as follows: Almond at 0.02 parts per million (ppm); almond, hulls at 4.0 ppm; berry, low growing, subgroup 13–07G at 4.0 ppm; bushberry, subgroup 13–07B at 7.0 ppm; caneberry, subgroup 13–07A at 5.0 ppm; fish-freshwater finfish at 0.01 ppm; fish-shellfish, crustacean at 0.01 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.0 ppm; grape, raisin at 5.7 ppm; hog, meat byproducts at 0.01 ppm; pecan at 0.06 ppm; rice, bran at 8.5 ppm; rice, grain at 5.0 ppm; rice, hulls at 15.0 ppm; sugarcane, cane at 3.0 ppm; vegetable, brassica leafy, group 5 at 4.0 ppm; vegetable, bulb, group 3–07 at 1.5 ppm; vegetable, cucurbit, group 9 at 0.5 ppm; vegetable, leafy, except brassica, group 4 at 30.0 ppm; vegetable, root, except sugarbeet, subgroup 1B at 0.9 ppm. EPA issued a notice announcing the filing of the revised petition in the **Federal Register** of November 27, 2013 (78 FR 70906) (FRL–9902–87). That document referenced a summary of the revised petition prepared by BASF, which is available in docket EPA–HQ–OPP–2012–0638.

Three comments were received on the notices of filing. EPA's response to the comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data

and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluxapyroxad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluxapyroxad follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Fluxapyroxad is of low acute toxicity by the oral, dermal and inhalation routes, is not irritating to the eyes and skin, and is not a dermal sensitizer. The primary target organ for fluxapyroxad exposure via the oral route is the liver with secondary toxicity in the thyroid for rats only. Liver toxicity was observed in rats, mice, and dogs, with rats as the most sensitive species for all durations of exposure. In rats, adaptive effects of hepatocellular hypertrophy and increased liver weights and changes in liver enzyme activities were first observed. As the dose or duration of exposure to fluxapyroxad increased, clinical chemistry changes related to liver function also occurred, followed by hepatocellular necrosis, neoplastic changes in the liver, and tumors. Thyroid effects were observed only in rats. These effects were secondary to changes in liver enzyme regulation, which increased metabolism of thyroid hormone, resulting in changes in thyroid hormones, thyroid follicular hypertrophy and hyperplasia, and thyroid tumor formation. Tumors were not observed in species other than rats or in organs other than the liver and thyroid.

Fluxapyroxad is classified as ''Not likely to be Carcinogenic to Humans'' based on convincing evidence that carcinogenic effects are not likely below a defined dose range. There is no mutagenicity concern from *in vivo* or *in vitro* assays. The hypothesized mode of action (i.e., a non-genotoxic) for treatment related tumors (i.e., the liver and thyroid) was supported by a full panel of *in vitro* and *in vivo* studies that showed no evidence of genotoxicity, together with mechanistic studies in the liver and thyroid of rats that satisfied stringent criteria for establishing tumorgenic modes of action. The studies clearly identified the sequence of key events, dose-response concordance and temporal relationship to the tumor types. The Agency has determined that the chronic population adjusted dose (PAD) will adequately account for all chronic effects, including carcinogenicity that could result from exposure to fluxapyroxad because the points of departure (POD) for the chronic population adjusted dose (cPAD) is based on the most sensitive endpoint, liver effects. Effects in the liver preceded liver tumors and the effects observed in the thyroid (in rats only) were believed to be secondary to the liver effects.

No evidence of neurotoxicity was observed in response to repeated administration of fluxapyroxad. An acute neurotoxicity study showed decreased rearing and motor activity. This occurred on the day of dosing only and in the absence of histopathological effects or alterations in brain weights. This indicated that any neurotoxic effects of fluxapyroxad are likely to be transient and reversible due to alterations in neuropharmacology and not from neuronal damage. There were no neurotoxic effects observed in the subchronic dietary toxicity study. No evidence of reproductive toxicity was observed. Developmental effects observed in both rats and mice (thyroid follicular hypertrophy and hyperplasia in rats and decreased defecation, food consumption, body weight/body weight gain, and increased litter loss in rabbits) occurred at the same doses as those that caused adverse effects in maternal animals, indicating no quantitative susceptibility. Since the maternal toxicities of thyroid hormone perturbation in rats and systemic toxicity in rabbits likely contributed to the observed developmental effects there is low concern for qualitative susceptibility. An immunotoxicity study in mice showed no evidence of immunotoxic effects from fluxapyroxad.

Subchronic oral toxicity studies in rats, developmental toxicity studies in rabbits, and *in vitro* and *in vivo* genotoxicity studies were performed for fluxapyroxad metabolites F700F001, M700F002, and M700F048. Like fluxapyroxad, no genotoxic effects were observed for any of these metabolites. All three metabolites displayed lower subchronic toxicity via the oral route than fluxapyroxad, with evidence of non-specific toxicity (decreased body weight) observed only for M700F0048 at the limit dose. Only M700F0048 exhibited developmental toxicity at doses similar to those that caused developmental effects in rabbits with fluxapyroxad treatment. However, these effects (abortions and resorptions) were of a different nature than for fluxapyroxad (paw hyperflexion) and are considered secondary to maternal toxicity. The Agency considers these studies sufficient for hazard identification and characterization and concludes that these metabolites do not have hazards that exceed those of fluxapyroxad in nature, severity, or potency.

Specific information on the studies received and the nature of the adverse effects caused by fluxapyroxad as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Human Health Risk Assessment for Use of Fluxapyroxad on Numerous Crops'' at pp. 52 in docket ID number EPA–HQ–OPP–2012–0638.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological POD and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a PAD or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fluxapyroxad used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUXAPYROXAD FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children, and females 13–49 years of age).	NOAEL = 125 mg/kg/day UF_A = 10× UF_H = 10× FQPA SF = 1×	Acute RfD = 1.25 mg/kg/day. aPAD = 1.25 mg/kg/day.	Acute neurotoxicity study in rats. LOAEL = 500 mg/kg/day based on decreased motor activity and decreased rearing.
Chronic dietary (All populations)	NOAEL = 2.1 mg/kg/day UF_A = 10× UF_H = 10× FQPA SF = 1×	Chronic RfD = 0.021 mg/kg/day.. cPAD = 0.021 mg/kg/day.	Chronic toxicity/carcinogenicity study in rats. LOAEL = 11 mg/kg/day based on non-neoplastic changes in the liver (foci, masses).
Incidental oral short-term (1 to 30 days)	NOAEL = 9 mg/kg/day UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	28-day oral toxicity study in rats. LOAEL = 176 mg/kg/day based on changes in thyroid hormones and thyroid follicular hypertrophy/hyperplasia.
Dermal short- and intermediate-term (1 day to 6 months).	No hazard identified		28-day dermal toxicity study in rats. LOAEL = Not observed.
Inhalation short-term (1 to 30 days)	NOAEL= 9 mg/kg/day UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	28-day oral toxicity study in rats. LOAEL = 176 mg/kg/day based on changes in thyroid hormones and thyroid follicular hypertrophy/hyperplasia.
Inhalation intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL = 7.3 mg/kg/day. UF_A = 10× UF_H = 10× FQPA SF = 1×	LOC for MOE = 100	90-day dietary study in rats. LOAEL = 35.1 mg/kg/day based on thyroid follicular hypertrophy/hyperplasia.
Cancer (Oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans at doses sufficient to induce liver and/or thyroid tumors. Quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluxapyroxad, EPA considered exposure under the petitioned-for tolerances as well as all existing fluxapyroxad tolerances in 40 CFR 180.666. EPA assessed dietary exposures from fluxapyroxad in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for fluxapyroxad. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance level residues adjusted upward to account for metabolites of concern not included in the tolerance expression, 100 percent crop treated (PCT) assumptions, and dietary exposure evaluation model (DEEM) default and empirical processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, a moderately refined chronic dietary exposure analysis was performed. An assumption of 100 PCT and DEEM default and empirical processing factors were used for the chronic dietary analysis. Combined average field trial residues for parent and highest average field trial residues for metabolites of concern were used for all plant commodities. For livestock commodities tolerance level residues adjusted upward to account for metabolites of concern not included in the tolerance expression were used.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to fluxapyroxad. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on

the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluxapyroxad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluxapyroxad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Tier 1 Rice Model and the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluxapyroxad for acute exposures are estimated to be 127 parts per billion (ppb) for surface water and 203 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 127 ppb for surface water and 184 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 203 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 184 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fluxapyroxad is registered for the following uses that could result in residential exposures: residential turf. EPA assessed residential exposure using the following assumptions: Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Since no dermal hazard was identified for fluxapyroxad, MOEs were calculated for the inhalation route of exposure only.

Both adults and children may be exposed to fluxapyroxad residues from contact with treated lawns. Adult postapplication exposures were not quantitatively assessed since no dermal hazard was identified for fluxapyroxad and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil. Post application hand-to-mouth and object-to-mouth exposures are expected to be short-term (1 to 30 days) in duration due to the intermittent nature of applications in residential environments. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found fluxapyroxad to share a common mechanism of toxicity with any other substances, and fluxapyroxad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluxapyroxad does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of quantitative susceptibility was observed in a reproductive and developmental toxicity study in rats or in developmental toxicity studies in rats and rabbits. Developmental toxicity data in rats showed decreased body weight and body weight gain in the offspring at the same dose levels that caused thyroid follicular hypertrophy/hyperplasia in parental animals. Effects in rabbits were limited to paw hyperflexion, a malformation that is not considered to result from a single exposure and that usually reverses as the animal matures. Developmental effects observed in both rats and rabbits occurred at the same doses as those that caused adverse effects in maternal animals, indicating no quantitative susceptibility. The Agency has low concern for developmental toxicity because the observed effects were of low severity, were likely secondary to maternal toxicity, and demonstrated clear NOAELs. Further, the NOAELs for these effects were at dose levels higher than the points of departure selected for risk assessment for repeat-exposure scenarios. Therefore, based on the available data and the selection of risk assessment endpoints that are protective of developmental effects, there are no residual uncertainties with regard to pre- and/or postnatal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1×. That decision is based on the following findings:

i. The toxicity database for fluxapyroxad is complete. Although no subchronic inhalation data is available EPA has waived that data requirement based on, among other things, its conclusion that even if an additional 10× safety factor was applied, inhalation exposure would not raise a risk of concern.

ii. There is no indication that fluxapyroxad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Neither the acute or the subchronic neurotoxicity studies indicated specific neurotoxicity responses to fluxapyroxad. Because fluxapyroxad can disrupt thyroid

hormone levels, the Agency considered the potential for fluxapyroxad to cause developmental neurotoxicity as a result of thyroid hormone disruption, which is more sensitive endpoint than the endpoints used in a developmental neurotoxicity study. Based on its evaluation of thyroid hormone data submitted for fluxapyroxad and the ontogeny of thyroid hormone metabolism, the Agency has determined that adverse thyroid hormone disruptions in the young are unlikely to occur at dose levels as low as the points of departure chosen for risk assessment. The Agency has low concern for neurotoxic effects of fluxapyroxad at any life stage.

iii. Based on the developmental and reproductive toxicity studies discussed in Unit III.D.2., there are no residual uncertainties with regard to prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or field trial residue data. The dietary risk assessment is based on reliable data, is conservative and will not underestimate dietary exposure to fluxapyroxad. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluxapyroxad in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluxapyroxad.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluxapyroxad will occupy 12% of the aPAD for children 3–5 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluxapyroxad from food and water will utilize 64% of the cPAD for infants (< 1year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluxapyroxad is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluxapyroxad is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluxapyroxad. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 320 for adults and 560 for children. Because EPA's level of concern for fluxapyroxad is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, fluxapyroxad is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluxapyroxad.

5. *Aggregate cancer risk for U.S. population.* EPA classified fluxapyroxad as ''Not likely to be Carcinogenic to Humans'' based on convincing evidence that carcinogenic effects are not likely below a defined dose range. The Agency has determined that the quantification of risk using the cPAD for fluxapyroxad will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluxapyroxad. The POD for the cPAD is based on the most sensitive endpoint, liver effects. Effects in the liver preceded liver tumors and the effects observed in the thyroid (in rats only) were believed to be secondary to the liver effects. As noted above, chronic exposure to fluxapyroxad from food and water will utilize 64% of the cPAD for infants (< 1year old) the population group receiving the greatest exposure.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluxapyroxad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A Liquid Chromatography-Mass Spectrometer/Mass Spectrometer (LC/MS/MS) method is available as an enforcement method. This method uses reversed-phase High Pressure Liquid Chromatography (HPLC) with gradient elution, and includes 2 ion transitions to be monitored for the parent fluxapyroxad.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for fluxapyroxad on the commodities subject in this notice.

C. Response to Comments

Three anonymous public comments were received opposing establishment

of the requested tolerances. The first commenter alleges that there is already too much toxicity from pesticide chemicals in the U.S. and EPA should not allow more pesticide residues on food. The second commenter claims that a data gap exists for maximum residues of fluxapyroxad in wheat and for accumulation of fluxapyroxad residues in soil and argues that EPA should require testing of pesticides when combined with other pesticides. The third anonymous commenter states that the U.S. should no longer allow the importation of pet foods from China. The Department of Utility, City of Sacramento, California submitted a comment on the application by BASF to register fluxapyroxad for use on rice under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. Several issues in that comment pertain to EPA's risk assessment for the fluxapyroxad tolerance petition. The Department of Utility expresses concern with the potential human health effects of breakdown products (metabolites, degradates, transformations products) that occur both prior and subsequent to water treatment, the effects of water treatment on the removal of fluxapyroxad residues, and the potential synergistic effects from exposure to multiple rice pesticides in drinking water.

The anonymous commenters either raise irrelevant or non-specific issues, make unsubstantiated claims, or are mistaken in their allegations. General claims regarding the toxicity of other pesticides and objections to the import of pet food from China do not raise safety concerns regarding EPA's assessment of the risk from aggregate exposure to fluxapyroxad. With regard to potential cumulative effects from the interaction of fluxapyroxad with other substances, EPA has addressed this issue in Unit III. C. 4., above. Finally, the commenter who claims there are data gaps is mistaken. The Agency determined that the available residue chemistry data for fluxapyroxad are sufficient to support the established tolerances for registered wheat uses. No data gaps were identified for wheat commodities or for rotational crop commodities. Additionally, the fluxapyroxad product label statements restrict crop rotation to commodities listed on the label.

The remaining comments raised by Sacramento's Department of Utility express concerns with EPA's examination of breakdown products from fluxapyroxad, and fluxapyroxad residue removal through water treatment in a drinking water plant. EPA possesses a full complement of standard metabolism and environmental fate studies on fluxapyroxad, as specified under 40 CFR 158.1300 and 158.1410. These include hydrolysis (OCSPP Guideline 835.2120), aqueous photolysis (OCSPP Guideline 835.2240), aerobic soil metabolism, and aerobic aquatic metabolism studies (OCSPP Guidelines 835.4100/4200 and 835.4300/4400). While these studies provide general information on the fate of fluxapyroxad and its metabolites in the environment, they do not directly address the chemicals' fate during drinking water treatment, and were therefore used only for qualitative characterization of such effects. The studies show that fluxapyroxad is stable to hydrolysis and aquatic degradation, therefore the chemical is not expected to degrade during drinking water treatment, and/or subsequent delivery of treated water to the consumer's tap. Because fluxapyroxad is moderately to slightly mobile in soils, treatment methods such as sedimentation, flocculation, and activated carbon filtration are expected to have some effect at removing fluxapyroxad. Available studies also show that fluxapyroxad does not degrade via photolysis, therefore where ultraviolet light is used as a means of disinfection, enhanced degradation of fluxapyroxad is not expected to occur. The chemical structure of fluxapyroxad does not appear to include any moieties where oxidation due to water chlorination could result in the formation of an obviously more-toxic transformation product, such as an oxon. EPA possesses toxicity data on various fluxapyroxad metabolites and degradates. The data indicate that none of these metabolites are more toxic than parent fluxapyroxad, and they were therefore not considered as separate entities in dietary or drinking water risk assessments. In conclusion, based upon the available information, EPA believes that it has adequately taken drinking water treatment into account in addressing potential human health risks from fluxapyroxad. EPA does not routinely require data on the effects of water treatment processes on pesticides. Rather, in assessing risks, EPA generally employs (as it did with fluxapyroxad) estimates of pesticide concentrations in source (untreated) water as a surrogate for concentrations in consumed water. This approach is inherently conservative, and is therefore expected to be protective of public health.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petitions, petition PP 2F8058 was revised by decreasing the proposed tolerances for nongrass animal feeds, group 18 from 0.5 to 0.30 ppm; and mint from 0.05 to 0.01 ppm. In addition, the Agency is amending the existing tolerance for grain, cereal, group 15, by adding ''except rice'' to the commodity definition. In lieu of the proposed tolerances for almonds and pecans, and since these are the representative commodities for the tree nut crop group, the Agency is establishing a tolerance for the tree nut crop group 14–12 at 0.06 ppm.

The Agency concluded that based on the residue data these changes are required to support the proposed uses. The Agency analyzed the field trial data for the respective commodities using the Organization for Economic Cooperation and Development tolerance calculation procedures to determine the appropriate tolerances.

V. Conclusion

Therefore, tolerances are established for residues of fluxapyroxad, 3-(difluoromethyl)-1-methyl-N-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide, as requested in the revised petitions.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income

Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 14, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.666:

■ a. Revise the following commodities in the table in paragraph (a): ''Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except wheat)'' and ''Fruit, stone, group 12.''

■ b. Add alphabetically 21 commodities to the table in paragraph (a).

■ c. Revise paragraph (d).

The revisions and additions read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Almond, hulls	4.0
* * * * * * *	
Berry, low growing, subgroup 13–07G	4.0
Bushberry, subgroup 13–07B	7.0
Caneberry, subgroup 13–07A	5.0
* * * * * * *	
Fish-freshwater finfish	0.01
Fish-shellfish, crustacean	0.01
* * * * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2.0
* * * * * * *	
Fruit, stone, group 12–12	3.0
* * * * * * *	
Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except rice; except wheat	3.0
* * * * * * *	
Grape, raisin	5.7
Hog, meat byproducts	0.01
* * * * * * *	
Nut, tree, group 14–12	0.06
* * * * * * *	
Rice, bran	8.5
Rice, grain	5.0
Rice, hulls	15.0
* * * * * * *	
Sugarcane, cane	3.0

Commodity	Parts per million
* * * * * * *	
Vegetable, brassica leafy, group 5	4.0
Vegetable, bulb, group 3–07	1.5
Vegetable, cucurbit, group 9	0.50
* * * * * * *	
Vegetable, leafy, except brassica, group 4	30
* * * * * * *	
Vegetable, root, except sugarbeet, subgroup 1B	0.90
* * * * * * *	

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the combined indirect or inadvertent residues of the fungicide fluxapyroxad, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluxapyroxad, 3-(difluoromethyl)-1-methyl-N-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide in or on the commodity.

Commodity	Parts per million
Nongrass animal feeds, group18	0.30
Peppermint, tops	0.01
Spearmint, tops	0.01

[FR Doc. 2014–04164 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0093; FRL–9906–17]

N-(n-octyl)-2-pyrrolidone; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687–94–7) when used as an inert ingredient (solvent) in formulations of pyraflufen-ethyl herbicide at a maximum concentration of 20% weight. Wagner Regulatory Associates on behalf of Nichino America, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of N-(n-octyl)-2-pyrrolidone.

DATES: This regulation is effective February 26, 2014. Objections and requests for hearings must be received on or before April 28, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0093, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0093 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 28, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your

objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0093, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL–9380–2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN–10541) by Nichino America, Inc. 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180.1130 be amended by establishing an exemption from the requirement of a tolerance for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687–94–7) when used as an inert ingredient (solvent) in formulations of pyraflufen-ethyl herbicide at a maximum concentration of 20% weight. That document referenced a summary of the petition prepared by Wagner Regulatory Associates, Inc. 7217 Lancaster Pike, Suite A, P.O. Box 640, Hockessin, Delaware 19707, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for N-(n-octyl)-2-pyrrolidone including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with N-(n-octyl)-2-pyrrolidone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by N-(n-octyl)-2-pyrrolidone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Based on the results of acute toxicity studies in rats, N-(n-octyl)-2-pyrrolidone is classified as having low acute toxicity via the oral and dermal routes of exposure. It is a dermal irritant and a dermal sensitizer.

In mammals, the primary target is the liver. In subchronic feeding studies in rats and dogs, N-(n-octyl)-2-pyrrolidone generally caused increases in both absolute and relative liver weights along with reduction in body weight gain/food consumption and changes in hematological and biochemical parameters. No chronic toxicity study is available.

In a developmental toxicity study in rats with N-(n-octyl)-2-pyrrolidone, there was no evidence of increased susceptibility in fetuses as toxic effects were observed only at the highest dose tested, 800 milligrams/kilograms/day (mg/kg/day), in which dams exhibited ruffled fur, ventral recumbency, somnolence, apathy, dyspnea and comatose state. Other adverse effects observed were a reduction in food consumption and slight body weight loss during the first days of dosing and reduced corrected body weight gain. Developmental effects such as reduced body weight and delay in skeletal ossification were observed only in the presence of maternal toxicity. No reproductive toxicity, immunotoxicity or neurotoxicity data are available for N-(n-octyl)-2-pyrrolidone,

There were three genotoxicity studies available in the database for N-(n-octyl)-2-pyrrolidone. An Ames test, a mouse

lymphoma assay and a mouse micronucleus test all showed negative results for genotoxicity of N-(n-octyl)-2-pyrrolidone.

No carcinogenicity studies were available in the database for N-(n-octyl)-2-pyrrolidone. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for potential carcinogenicity for N-(n-octyl)-2-pyrrolidone. No structural alerts for carcinogenicity were identified for N-(n-octyl)-2-pyrrolidone. In the absence of any structural alerts and lack of mutagenicity concerns, N-(n-octyl)-2-pyrrolidone is not expected to be carcinogenic.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for N-(n-octyl)-2-pyrrolidone used for human risk assessment is given below:

1. *Acute dietary (all populations).* There were no adverse effects observed attributable to a single dose for the general population (including infants and children) or females 13–49 years of age.

2. *Chronic dietary (all populations).* The chronic population adjusted dose (cPAD) was established based on the NOAEL (30 mg/kg/day) from a 90-day oral toxicity study in dogs. The adverse effects seen in this study were several statistically significant changes in hematology and clinical chemistry parameters and statistically significant dose-related increases in both absolute and relative liver weights at the LOAEL of 90 mg/kg/day. A Food Quality Protection Act (FQPA) safety factor/ database uncertainty factor of 3X is utilized for dietary risk assessment.

3. *Dermal, short-term (1–30 days).* The level of concern (LOC) for short-term dermal exposure is a Margin of Exposure (MOE) of 300 between estimated human exposure and the NOAEL (30 mg/kg/day) from the 90-day oral toxicity study in dogs. An FQPA safety factor/database uncertainty factor of 3X is utilized for dermal, short-term, assessment.

4. *Inhalation, short-term (1–30 days).* The level of concern (LOC) for short-term inhalation exposure is a MOE of 300 between estimated human exposure and the NOAEL (30 mg/kg/day) from the 90-day oral toxicity study in dogs. An FQPA safety factor/database uncertainty factor of 3X for the short-term inhalation assessment.

Quantification of cancer risk is not appropriate since there are no concerns for cancer based on SAR analysis of N-(n-octyl)-2-pyrrolidone.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to N-(n-octyl)-2-pyrrolidone, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from N-(n-octyl)-2-pyrrolidone in food as follows:

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM–FCID)™, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for N-(n-octyl)-2-pyrrolidone. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the case of N-(n-octyl)-2-pyrrolidone, EPA made specific adjustments to the dietary exposure assessment to account for the use limitations of N-(n-octyl)-2-pyrrolidone as an inert ingredient in cotton defoliant formulations containing thidiazuron and diuron as active ingredients as well as the proposed use as an inert ingredient in formulations of pyraflufen ethyl herbicide at a maximum concentration of 20% weight.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for N-(n-octyl)-2-pyrrolidone, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

The proposed use of N-(n-octyl)-2-pyrrolidone is as an inert ingredient in pyraflufen ethyl formulations which have uses resulting in potential residential exposures. A screening level residential exposure and risk assessment was conducted based on the use pattern and application rates of pyraflufen ethyl products.

EPA assessed residential exposure using the following assumptions: All residential exposures are considered short-term in duration. The residential handler assessment included short-term exposures via the dermal and inhalation routes from treating golf courses, ornamental turf lawns, road sides, parks and sports fields. In terms of post-application exposure, there is the potential for dermal post-application exposure for individuals as result of being in an environment that has been previously treated with N-(n-octyl)-2-pyrrolidone. Short-term dermal exposures were assessed for adults,

children 1–2 and adult/child golfer. The scenarios used in the aggregate assessment were those that resulted in the highest exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found N-(n-octyl)-2-pyrrolidone to share a common mechanism of toxicity with any other substances, and N-(n-octyl)-2-pyrrolidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that N-(n-octyl)-2-pyrrolidone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased susceptibility was seen in the developmental toxicity study on N-(n-octyl)-2-pyrrolidone. The maternal and developmental toxicity NOAEL was 200 mg/kg bw/day based on reduced body weight gain in dams and mean fetal body weight and delay in skeletal ossification at the LOAEL of 800 mg/kg bw/day. No reproductive toxicity study is available N-(n-octyl)-2-pyrrolidone.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3X for all scenarios. That decision is based on the following findings:

i. The toxicity database for N-(n-octyl)-2-pyrrolidone consists of 90-day oral toxicity studies in rats and dogs, several mutagenicity studies and a developmental toxicity study. While there are no reproductive, neurotoxicity and chronic toxicity studies for N-(n-octyl)-2-pyrrolidone, there is no evidence of effects on reproductive parameters or of any effects suggestive of neurotoxicity from the available subchronic studies. Additionally, the most sensitive endpoint selected seen in the 90-day dog oral toxicity study is based on hematological and clinical chemistry parameters; increases in both absolute and relative liver weights; and reduction in body weight gain/food consumption—effects which are not expected to be progressive and for which the resultant exposure assessment is likely to be protective of chronic effects and characterize toxicity potential of N-(n-octyl)-2-pyrrolidone. Although additional data are unlikely to indicate more sensitive effects, EPA has retained a FQPA factor of 3X as a database uncertainty factor. No inhalation toxicity studies were available in the database; however, the only potential inhalation exposure to N-(n-octyl)-2-pyrrolidone is to pesticide applicators, and, even assuming that such exposure has some relevance to decisions on the FQPA safety factor, the inhalation exposure to N-(n-octyl)-2-pyrrolidone is negligible in comparison to exposure under other pathways. In these circumstances, neither retention or removal of the FQPA safety factor would have a meaningful impact on assessment of risk from inhalation exposure.

ii. No evidence of immunotoxicity was observed in the available database. Slight change in the clinical pathological parameters (decreases in albumin/globulin ratio and globulin levels) were not considered as an indication of an immunotoxic response since no effects on blood lymphocytes and no adverse findings in the spleen and thymus. Therefore, an immunotoxicity study is not required.

iii. There are no residual uncertainties identified in the exposure databases. As described earlier, EPA used worst case assumptions for the dietary food exposure assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to N-(n-octyl)-2-pyrrolidone in drinking water. EPA used similarly conservative assumptions to assess residential post application exposure of children as well as incidental oral exposure of children 1–2. These assessments will not underestimate the exposure and risks posed by N-(n-octyl)-2-pyrrolidone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, N-(n-octyl)-2-pyrrolidone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to N-(n-octyl)-2-pyrrolidone from food and water will utilize 59.37% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. The chronic dietary exposure estimates for the total U.S. population was 14.31%.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). N-(n-octyl)-2-pyrrolidone is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to N-(n-octyl)-2-pyrrolidone.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,122 for adults and 291 for children 1–2. EPA's level of concern for N-(n-octyl)-2-pyrrolidone is a MOE of 300 or below, however these MOEs are not of concern based on the highly conservative assumptions made regarding residential and dietary exposures to N-(n-octyl)-2-pyrrolidone.

4. *Intermediate-term risk.* Intermediate-term residential aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyraflufen ethyl is not currently registered for uses that could result in intermediate-term residential exposure so an intermediate term risk assessment for N-(n-octyl)-2-pyrrolidone was not performed. There are also no intermediate-term adverse effects identified and therefore N-(n-octyl)-2-pyrrolidone is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* N-(n-octyl)-2-pyrolidone is not expected to be carcinogenic.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to N-(n-octyl)-2-pyrrolidone residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of N-(n-octyl)-2-pyrrolidone in or on any food commodities. EPA is establishing a limitation on the amount of N-(n-octyl)-2-pyrrolidone that may be used in pesticide formulations.

The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide for sale or distribution containing pyraflufen ethyl as an active ingredient with concentrations of N-(n-octyl)-2-pyrrolidone exceeding 20% by weight of the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for N-(n-octyl)-2-pyrrolidone.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.1130 for N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687–94–7) when used as an inert ingredient (solvent) in formulations of pyraflufen-ethyl herbicide at a maximum concentration of 20% by weight.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 18, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Revise § 180.1130 to read as follows:

§ 180.1130 N-(n-octyl)-2-pyrrolidone and N-(n-dodecyl)-2-pyrrolidone; exemptions from the requirement of a tolerance.

(a) *N*-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone are exempt

from the requirement of a tolerance when used as solvents in cotton defoliant formulations containing thidiazuron and diuron as active ingredients.

(b) *N*-(*n*-octyl)-2-pyrrolidone is exempt from the requirement of a tolerance when used as a solvent in formulations containing pyraflufen-ethyl as an active ingredient at a concentration not to exceed 20% by weight.

[FR Doc. 2014–04099 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0389; FRL–9904–92]

GS-omega/kappa-Hxtx-Hv1a; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of GS-omega/kappa-Hxtx-Hv1a, in or on all food commodities when applied or used in accordance with label directions and good agricultural practices. Vestaron Corporation, submitted a petition to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of GS-omega/kappa-Hxtx-Hv1a under FFDCA.

DATES: This regulation is effective February 26, 2014. Objections and requests for hearings must be received on or before April 28, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0389, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by the EPA, you must identify docket ID number EPA–HQ–OPP–2012–0389 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 28, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by the EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0389, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL–9353–6), the EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F8014) by Vestaron Corporation, 4717 Campus Drive, Ste. 1200, Kalamazoo, MI 49008. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of GS-omega/kappa-Hxtx-Hv1a. That document referenced a summary of the petition prepared by the petitioner Vestaron Corporation, which is available in the docket, *http://www.regulations.gov.* No comments to the petition for GS-U-ACTX-Hv1a-SEQ2 tolerance exemption were received. A correction for the name of the active ingredient was published in the **Federal Register** of December 18, 2013 (78 FR 76589) (FRL–9904–17). The active ingredient, previously known as GS-U-ACTX-Hv1a-SEQ2, was revised to GS-omega/kappa-Hxtx-Hv1a, based on acceptable nomenclature for naming peptide toxins from spiders.

III. Final Rule

A. The EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows the EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if the EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, the EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require the EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of (a particular pesticide's) residues . . . and other substances that have a common mechanism of toxicity.''

The EPA evaluated the available toxicity and exposure data on GS-omega/kappa-Hxtx-Hv1a and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. Based upon that evaluation, the EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of GS-omega/kappa-Hxtx-Hv1a. Therefore, an exemption from the requirement of a tolerance is established for residues of GS-omega/kappa-Hxtx-Hv1a in or on all food commodities when applied or used in accordance with label directions and good agricultural practices. A full explanation of the data upon which the EPA relied and its risk assessment based on that data can be found within the November 21, 2013 document entitled ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for GS-omega/kappa-Hxtx-Hv1a.'' This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

In making its tolerance decisions, the EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. The EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. The EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that the EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for GS-omega/kappa-Hxtx-Hv1a.

IV. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 3, 2014.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1324 to subpart D to read as follows:

§ 180.1324 GS-omega/kappa-Hxtx-Hv1a; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticide GS-omega/kappa-Hxtx-Hv1a in or on all food commodities when applied or used in accordance with label directions and good agricultural practices.

[FR Doc. 2014–04092 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 206

[Docket ID FEMA–2014–0009]

RIN 1660–AA81

Amendment to the Public Assistance Program's Simplified Procedures Project Thresholds

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA) is revising two dollar figures in its regulations governing the Public Assistance Program's project thresholds. FEMA is revising the monetary thresholds for when FEMA will process an application using ''simplified procedures.''

DATES: This rule is effective February 26, 2014.

FOR FURTHER INFORMATION CONTACT: Liza Davis, Associate Chief Counsel, Regulatory Affairs, Office of Chief Counsel, FEMA, 202–646–4046, *liza.davis@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: FEMA's Public Assistance program provides grants to State, Tribal, and local governments, as well as eligible private nonprofit organizations, for debris removal, emergency protective measures, and the repair, replacement, or restoration of disaster-damaged facilities after a Presidentially-declared major disaster.[1] Each grant award is categorized as either a large or small project, which is determined by a monetary threshold set each year by FEMA pursuant to statute.[2] The maximum threshold for FY2014 is $68,500;[3] all projects below this amount are categorized as small projects, and all projects at or above this amount are categorized as large projects. In addition, each project must meet a minimum threshold of $1,000.[4]

The Sandy Recovery Improvement Act of 2013 (SRIA)[5] required FEMA to analyze the Public Assistance project thresholds and, within one year of SRIA's passage, to submit a report to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate with its findings.[6] On January 29, 2014, FEMA submitted this report to Congress, and a copy is included in the docket for this rule on *www.regulations.gov* under docket ID FEMA–2014–0009.[7] In the report, FEMA recommends a maximum threshold of $120,000, and a minimum threshold of $3,000.

SRIA requires FEMA to implement the new thresholds ''immediately'' following submission of the report to the Congress and ''without regard to chapter 5 of title 5, United States Code.''[8] Accordingly, this action updates FEMA's Public Assistance regulations with the new thresholds, which will both be adjusted annually to reflect changes in the Consumer Price Index for All Urban Consumers published by the Department of Labor.[9]

FEMA will be publishing a notice in the **Federal Register** in the near future to seek public comment on the report for the purpose of informing future revisions to the thresholds. SRIA requires FEMA to review the thresholds every three years.[10]

Administrative Procedure Act

Generally, the Administrative Procedure Act (APA) requires a Federal agency to provide the public with notice and the opportunity to comment on agency rulemakings.[11] Section 1107 of SRIA, however, directs FEMA to ''immediately establish a threshold for eligibility under this section in an appropriate amount, without regard to [5 U.S.C. chapter 5].'' Accordingly, this action is not covered by the APA's requirements related to notice-and-comment rulemaking, and FEMA is immediately establishing the new threshold for eligibility in the Code of Federal Regulations. By implementing the new thresholds via a final rule, FEMA meets the requirement of SRIA to implement the new thresholds ''immediately'' and without the delay of a proposed rule and public comment period.

The action is limited to updating two dollar figures related to FEMA's procedures for handling certain grants (the minimum and maximum thresholds for PA projects) and adding the annual update requirement for the minimum threshold to reflect changes in the Consumer Price Index for All Urban Consumers published by the Department of Labor.[12]

For the same reasons discussed above, FEMA is implementing this change without the 30-day delayed effective date usually required under section 553(d)(3) of the APA, as such a delay would be contrary to section 1107's requirement to implement the thresholds ''immediately.''

List of Subjects in 44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs-housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs-housing and community development, Natural resources, Penalties, and Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Federal Emergency

[1] The Public Assistance program is authorized by the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. 5170b, 5172, 5173, 5192.

[2] See 42 U.S.C. 5189; 44 CFR 206.203(c), 206.205. FEMA obligates money for a small project based on an estimate of the project cost; FEMA obligates money for a large project based on actual project costs as the project progresses and cost documentation is provided to FEMA. See 44 CFR 206.203(c); Public Assistance Guide, FEMA 322 (June 2007), Chapter 3, ''Applying for Public Assistance,'' ''Project Formulation'' available *at http://www.fema.gov/public-assistance-local-state-tribal-and-non-profit/public-assistance-guide-3.*

[3] See 78 FR 64232 (Oct. 28, 2013).

[4] 44 CFR 206.202(d)(2).

[5] Public Law 113–2, section 1107, codified in relevant part at 42 U.S.C. 5189.

[6] See 42 U.S.C. 5189(b)(1).

[7] A copy of the report is also available at *http://www.fema.gov/media-library/assets/documents/90458.*

[8] See 42 U.S.C. 5189(b)(2)(A).

[9] See 5 U.S.C. 5189(b)(2)(B).

[10] See 42 U.S.C. 5189(b)(3).

[11] See 5 U.S.C. 553.

[12] FEMA's current regulations require only a periodic review of the minimum threshold. See 44 CFR 206.202(d)(2). Section 1107 of SRIA, however, requires an annual update based on the Consumer Price Index for All Urban Consumers published by the Department of Labor.

Management Agency amends 44 CFR part 206 as follows:

PART 206—FEDERAL DISASTER ASSISTANCE

■ 1. The authority citation for part 206 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; Homeland Security Act of 2002, 6 U.S.C. 101 et seq.; Department of Homeland Security Delegation 9001.1; sec. 1105, Pub. L. 113–2, 127 Stat. 43 (42 U.S.C. 5189a note).

■ 2. In § 206.202, in paragraph (d)(2), remove ''$1,000'' and add in its place ''$3,000'' and revise the second sentence to read as follows:

§ 206.202 Application procedures.

* * * * *

(d) * * *

(2) * * * Such $3,000 amount shall be adjusted annually to reflect changes in the Consumer Price Index for All Urban Consumers published by the Department of Labor.

* * * * *

§ 206.203 [Amended]

■ 3. In § 206.203, in paragraphs (c)(1) and (2), remove the number ''$35,000'' and add, in its place, the number ''$120,000'' wherever it appears.

Dated: February 20, 2014.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2014–04220 Filed 2–25–14; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 1, 10, 11, 12, 13, 14, and 15

[Docket No. USCG–2014–0016]

Policy Implementing the Standards of Training, Certification and Watchkeeping Final Rule; Notice of Availability

AGENCY: Coast Guard, DHS.

ACTION: Notification of availability.

SUMMARY: The Coast Guard announces the availability of nine Navigation and Vessel Inspection Circulars (NVICs), which are the first set of a series of NVICs to implement the final rule that aligned Coast Guard regulations with amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, and made changes to national endorsements. These NVICs will provide guidance to mariners concerning new regulations governing merchant mariner certificates and endorsements to Merchant Mariner Credentials (MMC).

DATES: These NVICs are effective on February 26, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions about this document, call or email Luke B. Harden, Mariner Credentialing Program Policy Division (CG–CVC–4), U.S. Coast Guard; telephone 202–372–2357, or *MMCPolicy@uscg.mil.* If you have questions on viewing material in the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Viewing Documents

The nine NVICs listed below are available in the docket and can be viewed by going to *www.regulations.gov*, inserting USCG–2014–0016 in the ''Keyword'' box, and then clicking ''Search.''

Discussion

On December 24, 2014, the Coast Guard published a Final Rule in the **Federal Register** (78 FR 77796) to implement the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978 (STCW Convention), including the 2010 amendments to the STCW Convention, and the Seafarers' Training, Certification and Watchkeeping Code. The final rule also made changes to reorganize, clarify, and update regulations for credentialing merchant mariners. In the future, the Coast Guard will issue additional NVICs to provide further guidance on the implementation of the new regulations regarding merchant mariner certificates and endorsements to MMCs. The nine NVICs listed below represent the first phase of this effort:

1. Guidance on the Issuance of Medical Certificates (NVIC 01–14). This NVIC describes policy for the issuance of medical certificates to merchant mariners.

2. Grandfathering and Transitional Provisions for Merchant Mariner Credentials (NVIC 02–14). This NVIC describes grandfathering and transitional provisions for MMCs.

3. Guidelines for Approval of Training Courses and Programs (NVIC 03–14). This NVIC describes policy for documentation, submission, and approval of merchant mariner training.

4. Guidelines for Qualification for STCW Endorsements for Proficiency in Survival Craft and Rescue Boats Other Than Fast Rescue Boats (NVIC 04–14). This NVIC describes policy for merchant mariners to qualify for and renew MMC endorsements for Proficiency in Survival Craft and Proficiency in Survival Craft-Limited.

5. Guidelines for Qualification for STCW Endorsements for Proficiency in Fast Rescue Boats (NVIC 05–14). This NVIC describes policy for merchant mariners to qualify for and renew MMC endorsements for Proficiency in Fast Rescue Boats.

6. Guidelines for Qualification for STCW Endorsements as Rating Forming Part of a Navigational Watch (NVIC 06–14). This NVIC describes policy for merchant mariners to qualify for and renew MMC endorsements as Rating Forming Part of a Navigational Watch.

7. Guidelines for Qualification for STCW Endorsements as Rating Forming Part of an Engineering Watch (NVIC 07–14). This NVIC describes policy for merchant mariners to qualify for and renew MMC endorsements as Rating Forming Part of an Engineering Watch.

8. Guidelines for Qualification for STCW Endorsements for Basic Training (Formerly Basic Safety Training) (NVIC 08–14). This NVIC describes policy for merchant mariners to qualify for and renew endorsements to an MMC for Basic Training.

9. Guidelines for Qualification for STCW Endorsements for Advanced Firefighting (NVIC 09–14). This NVIC describes policy for merchant mariners to qualify for and renew MMC endorsements for Advanced Firefighting.

Although all of these NVICs are important to the implementation of the new regulations, note that NVICs 01–14, 02–14, and 03–14 will be particularly helpful during the beginning of the transition to those regulations.

Authority

This document is issued under the authority of 5 U.S.C. 552(a).

Dated: January 29, 2014.

Jonathan C. Burton,

Captain, U.S. Coast Guard, Director, Inspection & Compliance.

[FR Doc. 2014–04177 Filed 2–25–14; 8:45 am]

BILLING CODE 9110–04–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1815 and 1852

RIN 2700–AE13

NASA FAR Supplement: Proposal Adequacy Checklist

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: NASA has adopted as final, without change, a proposed rule amending the NASA FAR Supplement (NFS) to incorporate a proposal adequacy checklist for proposals in response to solicitations that require the submission of certified cost or pricing data.

DATES: *Effective Date:* March 28, 2014.

FOR FURTHER INFORMATION CONTACT: Bill Roets, NASA, Office of Procurement, Contract Management Division (Suite 5K34); (202) 358–4483; email: *william.roets-1@nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

A proposed rule was published on October 29, 2013 (78 FR 64442) that supported the NASA Assistant Administrator for Procurement's ''Reducing Transaction Costs in NASA Procurements'' initiative by incorporating the requirement for a proposal adequacy checklist into the NFS at 1815.408–70(c), and associated solicitation provision at NFS 1852.215–85, to ensure offerors take responsibility for submitting thorough, accurate, and complete proposals. The provision will be included in solicitations that require the submission of certified cost or pricing data.

B. Discussion and Analysis

I. Summary of Significant Changes

Based on a review of the public comments discussed below, NASA has concluded that no change to the proposed rule is necessary.

II. Analysis of Public Comment

NASA received comments from one respondent on the proposed rule. Comments are discussed below.

a. Overly Burdensome

Comment: Respondent opined that the proposed rule passed the administrative burden and shifted the associated costs directly onto the contractor which was inappropriate. Respondent suggested, as an alternative, that solicitations require standardized table of contents with a proposal.

Response: This rule does not impose additional requirements over what is already required under the conditions when certified cost or pricing data is required. This provision is a single uniform tool that is applicable across NASA to promote consistency in compliance with FAR Table 15–2.

b. Applicability Clarification

Comment: Respondent was concerned that this rule would be applied to programs that have a phased application process (e.g. Phase A, Phase B). Respondent requested clarification that the rule would only apply to the full (Phase B) application.

Response: The checklist is only utilized when certified cost or pricing data is required per FAR 15.403–4. In the example, if the Phase A acquisition did not require certified cost or pricing data, use of the checklist would not be required by this rule.

C. 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.

D. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, at 5 U.S.C. 601, et. seq., and is summarized as follows:

This final rule amends the NASA FAR Supplement (NFS) to add a checklist for NASA contractors to complete under solicitations that require the submission of certified cost or pricing data. This rule supports the NASA Assistant Administrator for Procurement's ''Reducing Transaction Costs in NASA Procurements'' initiative.

The objective of the rule is to ensure that offerors submit thorough, accurate, and complete proposals. By filling out the checklist, offerors will be able to self-validate their proposals.

No issues were raised by the public in response to the initial regulatory flexibility analysis.

No comments were filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the rule.

The final rule will apply to solicitations, for which certified cost or pricing data are required. Based on data collected in the Federal Procurement Data System for FY2010–2012, there are on average 1162 actions per year that met the criteria where the proposal adequacy checklist is to be utilized. On average, 462 of those actions are with small business concerns.

No alternatives were determined; the proposal adequacy checklist was created directly from requirements already in the FAR.

E. Paperwork Reduction Act

This final rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35). However, these changes to the NFS do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 9000–0013, entitled ''Cost or Pricing Data Exemption Information.''

List of Subjects in 48 CFR 1815 and 1852

Government Procurement.

William P. McNally,

Assistant Administrator for Procurement.

Accordingly, 48 CFR Parts 1815 and 1852 are amended as follows:

PART 1815—CONTRACTING BY NEGOTIATION

■ 1. The authority citation for Part 1815 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

■ 2. In section 1815.408–70, paragraph (c) is added to read as follows:

1815.408–70 NASA solicitation provisions and contract clauses.

* * * * *

(c) When the solicitation requires the submission of certified cost or pricing data, the contracting officer shall include 1815.215–85, Proposal Adequacy Checklist, in the solicitation to facilitate submission of a thorough, accurate, and complete proposal.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citation for Part 1852 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

■ 4. Section 1852.215–85 is added to read as follows:

1852.215–85 Proposal adequacy checklist.

As prescribed in 1815.408–70(c), use the following provision:

PROPOSAL ADEQUACY CHECKLIST (MAR 2014)

The offeror shall complete the following checklist, providing location of requested information, or an explanation of why the requested information is not provided. In preparation of the offeror's checklist, offerors may elect to have their prospective subcontractors use the same or similar checklist as appropriate.

PROPOSAL ADEQUACY CHECKLIST

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
	GENERAL INSTRUCTIONS		
1. FAR 15.408, Table 15–2, Section I Paragraph A.	Is there a properly completed first page of the proposal per FAR 15.408 Table 15–2 I.A or as specified in the solicitation?		
2. FAR 15.408, Table 15–2, Section I Paragraph A(7).	Does the proposal identify the need for Government-furnished material/tooling/test equipment? Include the accountable contract number and contracting officer contact information if known.		
3. FAR 15.408, Table 15–2, Section I Paragraph A(8).	If your organization is subject to Cost Accounting Standards (CAS), does the proposal identify the current status of your CAS Disclosure Statement? Does the proposal identify and explain notifications of noncompliance with Cost Accounting Standards Board or Cost Accounting Standards (CAS); any proposal inconsistencies with your disclosed practices or applicable CAS; and inconsistencies with your established estimating and accounting principles and procedures?		
4. FAR 15.408, Table 15–2, Section I, Paragraph C(1).	Does the proposal disclose any other known activity that could materially impact the costs?		
FAR 2.101, "Cost or pricing data"	This may include, but is not limited to, such factors as— (1) Vendor quotations; (2) Nonrecurring costs; (3) Information on changes in production methods and in production or purchasing volume; (4) Data supporting projections of business prospects and objectives and related operations costs; (5) Unit-cost trends such as those associated with labor efficiency; (6) Make-or-buy decisions; (7) Estimated resources to attain business goals; and (8) Information on management decisions that could have a significant bearing on costs.		
5. FAR 15.408, Table 15–2, Section I Paragraph B.	Is an Index of all certified cost or pricing data and information accompanying or identified in the proposal provided and appropriately referenced?		
6. FAR 15.403–1(b)	Are there any exceptions to submission of certified cost or pricing data pursuant to FAR 15.403–1(b)? If so, is supporting documentation included in the proposal? (Note questions 18–20.)		
7. FAR 15.408, Table 15–2, Section I Paragraph C(2)(i).	Does the proposal disclose the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data?		
8. FAR 15.408, Table 15–2, Section I Paragraph C(2)(ii).	Does the proposal disclose the nature and amount of any contingencies included in the proposed price?		
9. FAR 15.408 Table 15–2, Section II, Paragraph A or B.	Does the proposal explain the basis of all cost estimating relationships (labor hours or material) proposed on other than a discrete basis?		
10. FAR 15.408, Table 15–2, Section I Paragraphs D and E.	Is there a summary of total cost by element of cost and are the elements of cost cross-referenced to the supporting cost or pricing data? (Breakdowns for each cost element must be consistent with your cost accounting system, including breakdown by year.)		

PROPOSAL ADEQUACY CHECKLIST—Continued

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
11. FAR 15.408, Table 15–2, Section I Paragraphs D and E.	If more than one Contract Line Item Number (CLIN) or sub Contract Line Item Number (sub-CLIN) is proposed as required by the RFP, are there summary total amounts covering all line items for each element of cost and is it cross-referenced to the supporting cost or pricing data?		
12. FAR 15.408, Table 15–2, Section I Paragraph F.	Does the proposal identify any incurred costs for work performed before the submission of the proposal?		
13. FAR 15.408, Table 15–2, Section I Paragraph G.	Is there a Government forward pricing rate agreement (FPRA)? If so, the offeror shall identify the official submittal of such rate and factor data. If not, does the proposal include all rates and factors by year that are utilized in the development of the proposal and the basis for those rates and factors?		
COST ELEMENTS			
MATERIALS AND SERVICES			
14. FAR 15.408, Table 15–2, Section II Paragraph A.	Does the proposal include a consolidated summary of individual material and services, frequently referred to as a Consolidated Bill of Material (CBOM), to include the basis for pricing? The offeror's consolidated summary shall include raw materials, parts, components, assemblies, subcontracts and services to be produced or performed by others, identifying as a minimum the item, source, quantity, and price.		
SUBCONTRACTS (Purchased materials or services)			
15. FAR 15.404–3(c) ..... FAR 52.244–2	Per the thresholds of FAR 15.404–3(c), Subcontract Pricing Considerations, does the proposal include a copy of the applicable subcontractor's certified cost or pricing data?		
16. FAR 15.408, Table 15–2, Note 1; Section II Paragraph A.	Is there a price/cost analysis establishing the reasonableness of each of the proposed subcontracts included with the proposal? If the offeror's price/cost analyses are not provided with the proposal, does the proposal include a matrix identifying dates for receipt of subcontractor proposal, completion of fact finding for purposes of price/cost analysis, and submission of the price/cost analysis?		
EXCEPTIONS TO CERTIFIED COST OR PRICING DATA			
17. FAR 52.215–20 ..... FAR 2.101, "commercial item"	Has the offeror submitted an exception to the submission of certified cost or pricing data for commercial items proposed either at the prime or subcontractor level, in accordance with provision 52.215–20? a. Has the offeror specifically identified the type of commercial item claim (FAR 2.101 commercial item definition, paragraphs (1) through (8)), and the basis on which the item meets the definition? b. For modified commercial items (FAR 2.101 commercial item definition paragraph (3)); did the offeror classify the modification(s) as either— i. A modification of a type customarily available in the commercial marketplace (paragraph (3)(i)); or ii. A minor modification (paragraph (3)(ii)) of a type not customarily available in the commercial marketplace made to meet Federal Government requirements not exceeding the thresholds in FAR 15.403–1(c)(3)(iii)(B)? c. For proposed commercial items "of a type", or "evolved" or modified (FAR 2.101 commercial item definition paragraphs (1) through (3)), did the contractor provide a technical description of the differences between the proposed item and the comparison item(s)?		

PROPOSAL ADEQUACY CHECKLIST—Continued

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
18. FAR 15.408, Table 15–2, Section II Paragraph A(1).	Does the proposal support the degree of competition and the basis for establishing the source and reasonableness of price for each subcontract or purchase order priced on a competitive basis exceeding the threshold for certified cost or pricing data?		
INTERORGANIZATIONAL TRANSFERS			
19. FAR 15.408, Table 15–2, Section II Paragraph A.(2).	For inter-organizational transfers proposed at cost, does the proposal include a complete cost proposal in compliance with Table 15–2?		
20. FAR 15.408, Table 15–2, Section II Paragraph A(1).	For inter-organizational transfers proposed at price in accordance with FAR 31.205–26(e), does the proposal provide an analysis by the prime that supports the exception from certified cost or pricing data in accordance with FAR 15.403–1?		
DIRECT LABOR			
21. FAR 15.408, Table 15–2, Section II Paragraph B.	Does the proposal include a time phased (i.e.; monthly, quarterly) breakdown of labor hours, rates and costs by category or skill level? If labor is the allocation base for indirect costs, the labor cost must be summarized in order that the applicable overhead rate can be applied.		
22. FAR 15.408, Table 15–2, Section II Paragraph B.	For labor Basis of Estimates (BOEs), does the proposal include labor categories, labor hours, and task descriptions, (e.g.; Statement of Work reference, applicable CLIN, Work Breakdown Structure, rationale for estimate, applicable history, and time-phasing)?		
23. FAR subpart 22.10	If covered by the Service Contract Labor Standards statute (41 U.S.C. chapter 67), are the rates in the proposal in compliance with the minimum rates specified in the statute?		
INDIRECT COSTS			
24. FAR 15.408, Table 15–2, Section II Paragraph C.	Does the proposal indicate the basis of estimate for proposed indirect costs and how they are applied? (Support for the indirect rates could consist of cost breakdowns, trends, and budgetary data.)		
OTHER COSTS			
25. FAR 15.408, Table 15–2, Section II Paragraph D.	Does the proposal include other direct costs and the basis for pricing? If travel is included does the proposal include number of trips, number of people, number of days per trip, locations, and rates (e.g. airfare, per diem, hotel, car rental, etc)?		
26. FAR 15.408, Table 15–2, Section II Paragraph E.	If royalties exceed $1,500 does the proposal provide the information/data identified by Table 15–2?		
27. FAR 15.408, Table 15–2, Section II Paragraph F.	When facilities capital cost of money is proposed, does the proposal include submission of Form CASB–CMF or reference to an FPRA/FPRP and show the calculation of the proposed amount?		
FORMATS FOR SUBMISSION OF LINE ITEM SUMMARIES			
28. FAR 15.408, Table 15–2, Section III.	Are all cost element breakdowns provided using the applicable format prescribed in FAR 15.408, Table 15–2 III? (or alternative format if specified in the request for proposal).		
29. FAR 15.408, Table 15–2, Section III Paragraph B.	If the proposal is for a modification or change order, have cost of work deleted (credits) and cost of work added (debits) been provided in the format described in FAR 15.408, Table 15–2.III.B?		
30. FAR 15.408, Table 15–2, Section III Paragraph C.	For price revisions/redeterminations, does the proposal follow the format in FAR 15.408, Table 15–2.III.C?		

PROPOSAL ADEQUACY CHECKLIST—Continued

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
	OTHER		
31. FAR 16.4	If an incentive contract type, does the proposal include offeror proposed target cost, target profit or fee, share ratio, and, when applicable, minimum/maximum fee, ceiling price?		
32. FAR 16.203–4 and FAR 15.408 Table 15–2, Section II, Paragraphs A, B, C, and D.	If Economic Price Adjustments are being proposed, does the proposal show the rationale and application for the economic price adjustment?		
33. FAR 52.232–28	If the offeror is proposing Performance-Based Payments—did the offeror comply with FAR 52.232–28?		
34. FAR 15.408(n) FAR 52.215–22 FAR 52.215–23	Excessive Pass-through Charges—Identification of Subcontract Effort: If the offeror intends to subcontract more than 70% of the total cost of work to be performed, does the proposal identify: (i) the amount of the offeror's indirect costs and profit applicable to the work to be performed by the proposed subcontractor(s); and (ii) a description of the added value provided by the offeror as related to the work to be performed by the proposed subcontractor(s)?		

(End of provision)

[FR Doc. 2014–04210 Filed 2–25–14; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 120918468–3111–02]

RIN 0648–XD148

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Trawl Catcher Vessels in the Western Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2014 Pacific cod total allowable catch apportioned to trawl catcher vessels in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), February 23, 2014, through 1200 hours, A.l.t., June 10, 2014.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (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. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The A season allowance of the 2014 Pacific cod total allowable catch (TAC) apportioned to trawl catcher vessels in the Western Regulatory Area of the GOA is 6,191 metric tons (mt), as established by the final 2013 and 2014 harvest specifications for groundfish of the GOA (78 FR 13162, February 26, 2013) and inseason adjustment (79 FR 601, January 6, 2014).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the A season allowance of the 2014 Pacific cod TAC apportioned to trawl catcher vessels in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 5,791 mt and is setting aside the remaining 400 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA. After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 20, 2014.

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

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

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

Dated: February 21, 2014.

Emily H. Menashes,

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

[FR Doc. 2014–04190 Filed 2–21–14; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 79, No. 38

Wednesday, February 26, 2014

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 AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210 and 220

RIN 0584–AE25

Local School Wellness Policy Implementation Under the Healthy, Hunger-Free Kids Act of 2010

ACTION: Proposed rule.

SUMMARY: This proposed rule would require all local educational agencies participating in the National School Lunch Program and/or the School Breakfast Program to meet expanded local school wellness policy requirements consistent with the new requirements set forth in section 204 of the Healthy, Hunger-Free Kids Act of 2010. This proposed rule would establish the framework for the content of the local school wellness policies, ensure stakeholder participation in the development of such policies, and require periodic assessment of compliance and reporting on the progress toward achieving the goals of the local school wellness policy. This proposed rule would also require local educational agencies, as part of the local school wellness policy, to implement policies for the marketing of foods and beverages on the school campus during the school day consistent with nutrition standards for Smart Snacks. Additionally, this proposed rule would require each local educational agency to make information about local school wellness policy implementation for all participating schools available to the public on a periodic basis. The provisions of this proposed rulemaking would ensure local educational agencies establish and implement local school wellness policies that meet minimum standards designed to support a school environment that promotes sound nutrition and student health, reduces childhood obesity, and provides transparency to the public on school wellness policy content and implementation.

DATES: To be assured of consideration, written comments must be postmarked on or before April 28, 2014.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comments on this proposed rule. To be considered for this rulemaking, written comments must be submitted through one of the following methods:

- Preferred method: Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- Mail: Comments should be addressed to Julie Brewer, Chief, School Programs Branch, Policy and Program Development Division, Child Nutrition Programs, Food and Nutrition Service, P.O. Box 66740, St. Louis, Missouri 63166–6740.

Duplicate comments are not considered. Therefore, we request that commenters submit comments through only one of the methods listed above. All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Debra Nigri, Policy and Program Development Division, or Erika Pijai, Nutrition Promotion and Technical Assistance Division, Child Nutrition Programs, Food and Nutrition Service at (703) 305–2590.

SUPPLEMENTARY INFORMATION:

I. Background

Schools play a critical role in promoting student health, preventing childhood obesity, and combating problems associated with poor nutrition and physical inactivity. To formalize and encourage this role, section 204 of the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265), required each local educational agency (LEA) participating in the National School Lunch Program (NSLP) and/or the School Breakfast Program (SBP) to establish a local school wellness policy by School Year 2006.

The 2004 legislation placed the responsibility for developing a local school wellness policy at the local level, so the unique needs of each school under the jurisdiction of the LEA could be addressed. Each LEA was required to establish a local school wellness policy that set goals for nutrition education, physical activity, and other school-based activities designed to promote student wellness, and include nutrition guidelines for all foods available on the school campus during the school day. Additionally, LEAs were required to involve a broad group of individuals in the development of the local school wellness policy and to have a plan for measuring wellness policy implementation.

Subsequently, section 204 of the Healthy, Hunger-Free Kids Act of 2010 (HHFKA, Pub. L. 111–296, December 13, 2010) added a new section 9A to the Richard B. Russell National School Lunch Act (NSLA) (42 U.S.C. 1758b) which expands the scope of wellness policies; brings additional stakeholders into the development, implementation, and review of local school wellness policies; and requires public updates on the content and implementation of the wellness policies.

Specifically, section 9A of the NSLA, 42 U.S.C. 1758b, as added by the HHFKA, requires LEAs to establish local school wellness policies for all schools under the jurisdiction of the LEA, which, at a minimum, include:

- Goals for nutrition promotion and education, physical activity, and other school-based activities that promote student wellness (section 9A(b)(1) of the NSLA); and
- Nutrition guidelines for all foods available on each school campus during the school day consistent with USDA's meal pattern requirements and the nutrition standards for competitive foods, and designed to promote student health and reduce childhood obesity (section 9A(b)(2) of the NSLA).

In addition, section 9A requires LEAs to:

- Designate one or more LEA or school official(s), as appropriate, to ensure that each school complies with the local school wellness policy (section 9A(b)(5)(B) of the NSLA);
- Permit parents, students, representatives of the school food authority, teachers of physical education, school health professionals,

the school board, school administrators, and the general public to participate in the development, implementation, and periodic review and update of the local school wellness policy (section 9A(b)(3) of the NSLA); and

- Periodically measure and make available to the public an assessment on the implementation of the local school wellness policy, with specific information to be included (section 9A(b)(5)(A) of the NSLA).

New section 9A, as amended by the HHFKA, requires USDA to promulgate regulations that provide the framework and guidelines for LEAs to establish local school wellness policies. Therefore, this proposed rule would create a new section in the regulations governing NSLP, 7 CFR 210.30 *Local school wellness policy,* addressing the local school wellness policy requirements. This proposed rule also would amend the regulations governing the SBP, at 7 CFR 220.7, to include a cross reference to the local school wellness policy requirements in the NSLP regulations. The proposed requirements are discussed below.

Establishing a Local School Wellness Policy

Local School Wellness Policy Leadership

Developing a local school wellness policy that responds to the new NSLA requirements and meets the needs of the LEA requires thought, collaboration, and promotion. First and foremost, each LEA will need to establish local school wellness policy leadership, i.e., one or more LEA or school official(s) who fully understands the local school wellness requirements of the NSLA, who can facilitate the development and updates of the local school wellness policy, and who has the authority and responsibility to ensure that each school complies with the policy.

As required by section 9A(b)(5)(B) of the NSLA, as amended, this proposed rule, at § 210.30(e)(1), requires LEAs to designate one or more officials to ensure schools comply with the local school wellness policy. In addition, proposed § 210.30(c)(3) requires the LEA to identify within the written local school wellness policy, the position of the LEA or school official(s) responsible for oversight of the local school wellness policy to ensure each school's compliance with the policy.

Public Involvement in Local School Wellness Policy Development

Once leadership is identified, the next step would be to establish a diverse team made up of committed school and community stakeholders to assess the LEA's needs and develop a policy that both meets the operational realities of the LEA and works toward improved health and wellness outcomes for schoolchildren. This team may be part of an existing group within the LEA, such as a health and wellness committee, coordinated school health council, or other advisory group.

Section 9A(b)(3) of the NSLA, as amended, requires LEAs to allow parents, students, representatives of the school food authority, teachers of physical education, school health professionals, the school board, school administrators, and the general public to participate in the development, implementation, and periodic review and update of the local school wellness policy. This proposed rule, at § 210.30(d)(1), *Community involvement,* includes this requirement. In addition, proposed § 210.30(c)(4) would require each LEA to include in its written local school wellness policy, a plan for allowing the above-named individuals to participate in the development, implementation, and periodic review and update of the local school wellness policy.

While the statute and proposed regulations identify specific categories of stakeholders that must be permitted to participate, LEAs would have discretion in exactly how they implement this requirement. For example, there may not be individuals in each category of stakeholder within a school community, or they may not be willing or able to participate. Conversely, it may not be possible for an LEA to permit every interested individual in a particular category to participate. It may also be the case that there are additional categories of stakeholders within a school community that the LEA would like to include on the local school wellness policy team.

However, in convening a local school wellness policy team, LEAs are expected to actively seek members for the local school wellness policy team that represent each of the categories described in the statute, and to the extent practicable, allow them to participate. There are a variety of individuals to consider when seeking the right combination of representatives. For example, school health professionals may include health education teachers, school health services staff (i.e., nurses, physicians, dentists, health educators, and other allied health personnel who provide school health services), and mental health and social services staff (i.e., school counselors, psychologists, social workers, or psychiatrists). As another example, the general public may include a local dietitian, business representative, physician, medical professional, health care professional, parks and recreation representatives, community or civic leaders, farmer coalitions, or include local representation of organizations interested in children, nutrition, education, health, and physical activity.

LEAs are also encouraged to include Supplemental Nutrition Assistance Program Education (SNAP-Ed) coordinators or educators on the local school wellness policy committee, as appropriate. The Department's Supplemental Nutrition Assistance Program (SNAP) provides grants to State SNAP agencies to make nutrition education and obesity prevention services available to low-income persons to the extent that available resources permit. SNAP-Ed targets SNAP recipients and other low-income individuals defined as persons eligible to receive means-tested Federal assistance. The grants may be used for a variety of strategies and interventions, including supporting and/or providing nutrition education in classrooms and other settings, establishing community or school gardens in low-income areas, or collaborating with other organizations to implement obesity prevention services through public health or community-based approaches with environmental or policy-level strategies. SNAP-Ed providers may also be able to broaden the reach of a school's local school wellness activities through SNAP-Ed collaborative efforts with other publicly or privately funded national, state, and local nutrition education and health promotion initiatives and interventions. For additional information on SNAP-Ed, refer to *http://www.fns.usda.gov/snap/nutrition-education.*

The local school wellness policy teams may work at the LEA level, the school level, or both, depending on the size and structure of the LEA. The Department encourages both LEA level and school-level local school wellness teams to strengthen implementation and monitoring of wellness policies.

Once members of the local school wellness policy team are identified, the LEA is encouraged to make available to the public and school community, a list of names and position titles (or relationship to the school) of individuals who are a part of the school wellness policy team; as well as the name, position title, and contact information of the lead individual(s) or coordinator(s) for the LEA, and for each school as applicable.

Content of the Local School Wellness Policy

Nutrition Promotion and Education, Physical Activity, and Other School-Based Activities

The NSLA at section 9A(b)(1) requires that local school wellness policies include goals for nutrition promotion and education, physical activity, and other school based activities that promote student wellness. The proposed rule at § 210.30(c)(1) includes this requirement. Each area is discussed in more detail below, including information on these goals and how LEAs may address them.

In developing their local school wellness policy, LEAs should consider that effective policies include strong, clear goals with specific and measurable objectives and benchmarks stating *who* will make *what* change, by *how much, where,* and by *when,* with attention to both long- and short-term goals. General statements that do not have the *who, what, when,* or *where* components are not likely to provide schools clear direction and will compromise efforts to measure the schools' progress towards meeting wellness policy goals. Most measurable goals, objectives, and benchmarks will include numbers. USDA's technical assistance on local school wellness policies, discussed later in this preamble, will include examples of wellness policy goals, objectives and benchmarks for each of these areas.

Under the proposed rule at § 210.30(c)(1), LEAs would also be required to review and consider evidence-based strategies and techniques in establishing goals for nutrition promotion and education, physical activity, and other school based activities that promote student wellness. At a minimum, USDA would expect LEAs to review ''Smarter Lunchroom'' tools and strategies, which are evidence-based, simple, low-cost and no-cost changes that are shown to improve student participation in the NSLP an SBP while encouraging consumption of more whole grains, fruits, vegetables, and legumes, and decreasing plate waste (*http://healthymeals.nal.usda.gov/healthierus-school-challenge-resources/smarter-lunchrooms*). For example, using creative names for fruits and vegetables and targeted entrees, training staff to prompt students to select fruits and vegetables, placing unflavored milk in front of other beverage choices, and bundling ''grab and go'' meals that include fruit and vegetable items, have all been shown to improve the likelihood that children will make the healthier choice.

Nutrition promotion and education: The primary goal of nutrition promotion and education is to influence lifelong eating behaviors in a positive manner. Nutrition promotion includes evidence-based techniques and scientifically-based nutrition messages targeted to a specific audience to inspire and motivate them to take action and use these techniques and messages to create environments and food service venues (classroom, cafeteria, a la carte, vending machines, school store, snack bars, fundraisers, home, etc.) that encourage healthy nutrition choices, as well as enhance and encourage participation in school meal programs. Nutrition promotion specifically encourages children to participate in the NSLP and SBP. Research indicates that school meals are more healthful than what students eat as alternatives to school meals.[1] Nutrition promotion also includes the marketing and advertising of nutritious foods and beverages to students and is most effective when implemented consistently through a comprehensive and multi-channel approach by school staff and teachers, parents, students, and the community. Nutrition education teaches behavior-focused skills and may be offered as part of a comprehensive, standards-based program designed to provide students with the knowledge and skills necessary to promote their health and make positive choices regarding food and nutrition.

Local school wellness policy goals related to nutrition promotion and education might include activities such as:

- Including nutrition education as part of health education classes and/or stand-alone courses for all grade levels, including curricula that promote skill development, such as meal planning, recognizing food groups within a meal, understanding health information and food labels to evaluate the nutrient quality and contribution of foods;
- Integrating nutrition education into other core subjects such as math, science, language arts, and social sciences, as well as in non-core and elective subjects;
- Including nutrition and health posters, signage, or displays in the cafeteria food service and dining areas, classrooms, hallways, gymnasium, and/or bulletin boards that are frequently rotated, updated, or changed;
- Providing developmentally appropriate and culturally relevant participatory activities, such as contests, surveys, promotions, food demonstrations and taste-testing, voting for school meal recipe names, cafeteria design or décor challenges, farm visits, and school gardens; and
- Offering information to families that encourages them to teach their children about health and nutrition, and assists them in planning nutritious meals for their families (for example: handouts, newsletters, Parent Teacher Association/Organization (PTA/PTO) updates, Web site postings, presentations, workgroups, etc.).

USDA provides grade-appropriate curricula and lessons on nutrition education, as well as nutrition promotion materials through its Team Nutrition initiative. Team Nutrition provides participating schools with nutrition education and promotion materials and strategies that help focus attention on the important role nutritious school meals, nutrition education, and a health-promoting school environment play in helping students learn to enjoy healthy eating and physical activity. Team Nutrition provides a framework for team efforts by school food service personnel, teachers, parents, the media, and other community members, and supports LEA efforts to develop local school wellness policies. For more information on Team Nutrition, visit *http://teamnutrition.usda.gov/team.html*.

LEAs are also encouraged to include in their local school wellness policy any school-sponsored family wellness activities that include a nutrition component, partnerships with community health agencies or organizations (for example, to operate a school-based health center), partnerships with SNAP-Ed, and any community use of school facilities for nutrition-related activities.

Physical activity: The primary goals and characteristics of quality physical education and physical activity are to provide opportunities for every student to develop the knowledge and skills for specific physical activities; maintain physical fitness; reduce sedentary time; learn about cooperation, fair play, and responsible participation that meets the needs of all students (at all levels of physical ability); and gain an appreciation for lifelong physical activity through a healthy lifestyle.[2]

[1] According to the Student Nutrition and Dietary Assessment III study SNDA–III), students who consumed NSLP lunches consumed greater amounts of the nutrients recommended in the *Dietary Guidelines for Americans* than students who consumed lunches from home (see SNDA–III pp. 147–150).

[2] Department of Health and Human Services and the Department of Education. *Promoting Better Health for Young People Through Physical Activity*

Continued

Physical education and physical activity opportunities complement health education by instilling an understanding of the short-term and long-term benefits of a physically active and healthy lifestyle.

In addition to offering physical education, LEAs are encouraged to provide other opportunities for physical activity, outside of physical education, for every grade level. The Centers for Disease Control and Prevention's (CDC) recommendation for physical activity is 60 minutes each day for children and adolescents. Because children spend many hours at school, it is critical that schools offer time for students to meet the 60 minute goal. As examples, physical activity can include recess (outdoor and indoor) for elementary school students, classroom-based physical activity breaks to increase focus or teach academic content via physical movement, and opportunities for physical activity before and after school, such as intramural programs, interscholastic sports, and extracurricular community or club activities. Physical activity can also be incorporated into core subject areas (e.g. science, math, language, arts, social studies, etc.). LEAs are also encouraged to support teachers in incorporating opportunities for physical activity in the classroom whenever possible and in serving as role models by being physically active alongside the students.

In developing a local school wellness policy, an LEA could include goals, objectives and annual benchmarks for physical education and physical activity such as: Physical education amount and frequency requirements (i.e. days per week, and minutes per day/week); student fitness assessments and reporting to parents; policies on adaptive activities for students with physical limitations; waivers or exemptions that allow students to be exempted from taking physical education classes; and activities designed to teach students about a physically active lifestyle. LEAs are encouraged to develop outdoor and indoor recess guidelines or schedules, as well as policies on prohibiting the use of physical activity and withholding of physical education class and other forms of physical activity, such as recess, as punishment.

LEAs are also encouraged to include in their local school wellness policies school-sponsored family wellness activities that include a physical activity component; partnerships with community health agencies; the availability of safe facilities and equipment in sufficient quantities for all students to be active (including the frequency of inspections and replacements, as necessary); the community use of school grounds/facilities for physical activity outside of school hours; and strategies/events to promote safe, active routes to school (for example, ''walk to school day,'' crossing guards stationed around the school, and bicycle parking). Local public works, public safety, and/or police departments can be valuable partners in some of those efforts.

Other school-based activities: While nutrition education and promotion and physical activity are critical components, other school activities supporting nutrition and health are equally important in providing a healthy school nutrition environment. Wellness policy activities can and should be integrated across the entire school setting and are not limited to the cafeteria, other food and beverage venues, and school physical activity facilities. An LEA can take a coordinated approach to developing and implementing a wellness policy by addressing nutrition and physical activity through health education (including tobacco, alcohol and, other substance abuse prevention), physical education, school nutrition services, the physical environment, employee wellness, family engagement, community involvement, health services, and counseling, psychological, and social services. The wellness policy can support academic outcomes through activities that have a demonstrated link to academic performance such as classroom physical activity breaks [3] and breakfast.[4 5 6 7 8 9 10 11] While the examples listed below are not required, the Department encourages LEAs to address as many other school activities as possible to support a healthy school nutrition environment. For example, other activities that may be reflected into the local school wellness policy could include:

- Offering staff wellness activities and professional development opportunities related to health and nutrition that inspire school staff to serve as role models and practice healthy eating, physical activity, and other activities that support staff and student wellness;
- Applying for or being awarded a Healthier*US* School Challenge recognition (more information can be found at *http://teamnutrition.usda.gov/healthierUS/index.html)*;
- Completing and reporting the results of the School Health Index self-assessment process to assess the extent to which some or all components of the local school wellness policy are being implemented in schools. The Centers for Disease Control and Prevention's (CDC) free tool helps schools assess their strengths and weaknesses based on a comprehensive list of evidence-based guidelines and strategies that promote physical activity, nutrition, and other health behaviors; prioritize activities; and develop an action plan for improving student health, which can be incorporated into the School Improvement Plan. The *School Health Index* is available at *http://www.cdc.gov/healthyyouth/shi/*;
- Using CDC's *School Health Guidelines to Promote Healthy Eating and Physical Activity* to inform the policy development process, and identify specific evidence-based practices to include in the local school wellness policy. The *Guidelines* are available at: *http://www.cdc.gov/healthyyouth/npao/strategies.htm*;
- Sponsoring health fairs, TV-turnoff week,[12] school-supported races, family wellness activities, or family day activities that promote health and wellness;
- Incorporating school garden, Farm to School or Farm to Cafeteria, or Chefs

and Sports, A Report to the President From the Secretary of Health and Human Services and the Secretary of Education, 2000. Available from *http://www2.ed.gov/offices/OSDFS/physedapndc.pdf.*

[3] Centers for Disease Control and Prevention. The association between school-based physical activity, including physical education, and academic performance. Atlanta, GA: US Department of Health and Human Services; 2010. Available at *http://www.cdc.gov/healthyyouth/health_and_academics/pdf/pa-pe_paper.pdf.*

[4] Rampersaud GC, Pereira MA, Girard BL, Adams J, Metzl JD. Breakfast habits, nutritional status, body weight, and academic performance in children and adolescents. *J Am Diet* Assoc 2005; 105:743–60.

[5] Taras HL. Nutrition and student performance at school. *J Sch Health* 2005; 75:199–213.

[6] Hoyland A, Dye L, Lawton CL. A systematic review of the effect of breakfast on the cognitive performance of children and adolescents. *Nutr Res Rev* 2009; 22:220–43.

[7] Murphy JM, Pagano MR, Nachmani J, Sperling P, Kane S, Kleinman RR. The relationship of school breakfast to psychosocial and academic functioning. *Arch Pediatr Adolesc Med* 1998; 152:899–07.

[8] Kleinman R, Hall S, Green H, et al. Diet, breakfast, and academic performance in children. *Annals of Nutrition and Metabolism* 2002; 46(Supplement 1): S24–30.

[9] D'Anci KE, Constant F, Rosenberg IH. Hydration and Cognitive Function in Children. *Nutrition Reviews* 2006; 64(10): 457–464.

[10] Popkin BM, D'Anci KE, Rosenberg IH. Water, hydration, and health. *Nutrition Reviews* 2010; 68(8):439–458.

[11] Kempton MJ, Ettinger U, Foster R, Williams SCR, Calvart GA, Hampshire A, Zelaya FO, O'Gorman RL, McMorris T, Owen AM and Smith MS. Dehydration Affects Brain Structure and Function in Healthy Adolescents. *Human Brain Mapping* 2011; 32:71–79.

[12] See, for example, *http://www.screenfree.org/screentimefs.pdf* for a discussion of the possible ways TV-turnoff week may affect children.

Move to Schools activities that promote healthy eating;

• Sending families school newsletters or dedicated parts of newsletters or school Web sites promoting healthy eating, healthy recipes, physical activity, etc.;

• Incorporating practical and profitable healthy fundraisers that support nutrition education, physical activity, nutrition education and other wellness related activities (teacher jog-a-thon, fruit sale, recycled art sale); and

• Encouraging and promoting the use of *Let's Move* (*http://www.letsmove.gov/*) and other healthy initiatives that promote physical activity and healthy eating.

Nutrition Guidelines for All Foods

The NSLA, as amended at section 9A(b)(2), also requires that the local school wellness policy include nutrition guidelines for all foods available on each participating school campus under the jurisdiction of the LEA during the school day. These guidelines must be consistent with the regulations governing the meal pattern requirements for reimbursable meals under the NSLP and SBP (7 CFR 210.10 and 7 CFR 220.8) and the regulations governing competitive foods (7 CFR 210.11), which include foods and beverages, and promote student health and reduce obesity. This proposed rule, at § 210.30(c)(2), addresses this requirement, which is discussed in more detail below. This proposed rule also includes definitions at § 210.30(b) for the terms *school campus* and *school day.* These terms are defined in the same manner they are defined for the purpose of competitive foods at § 210.11(a). *School campus* means all areas of the property under the jurisdiction of the school that are accessible to students during the school day. *School day* means the period from the midnight before to 30 minutes after the end of the official school day.

School meals—Local school wellness policies can serve as a vehicle to explain to the public and the school community the updated nutrition standards for school meals as well as other State or local policies related to school meals. The Department promulgated a final rule, *Nutrition Standards in the National School Lunch and School Breakfast Program* (77 FR 4088), which updated the meal patterns and nutrition standards to align them with the *Dietary Guidelines for Americans.* The new meal pattern offers both fruits and vegetables each day, more whole grains, and portion sizes and calorie standards designed to maintain a healthy weight. To address school meals, the local school wellness policy could include information such as:

• An indication of whether the LEA is in compliance with the updated meal patterns;

• A description of the nutrition standards for school meals, emphasizing whole-grain offerings, fruit and vegetable offerings, low-fat and fat-free milk offerings, and compliance with the dietary specifications for calories, saturated fat, *trans* fat, and sodium;

• The Web site address (i.e., URL or uniform resource locator) where the school or LEA's current menus are available or the best method to view the current menus, if not posted online;

• A description of the Federal Child Nutrition programs in which the LEA participates (e.g., NSLP, SBP, Fresh Fruit and Vegetable Program, Summer Food Service Program, etc.), as well as any unique school meal activities that are provided, e.g., breakfast in the classroom, mobile breakfast carts, grab-and-go breakfast, breakfast after first period, afterschool snack program cart, etc;

• An indication of how participation in school meals programs will be promoted, how families are notified of the availability of the various Federal Child Nutrition Programs and how to determine students' eligibility to participate or a household's eligibility for free or reduced price meals;

• An indication if school meals are prepared onsite or offsite, and if a food service management company operates the school meal programs, or otherwise highlighting the school's ability to control recipes and ingredients;

• Policies relating to the school lunch and breakfast programs, e.g., substitutions for students with dietary restrictions, any special menus for students with special dietary needs, and any variations for various ethnic and cultural food preferences;

• Policies regarding the timing and duration of school meals that consider evidence-based research to support healthy eating (i.e., the periods or times in which school meals are offered; the amount of time allowed for students to eat breakfast and lunch at school, after being seated; recess before or after lunch); and

• Policies regarding the availability and locations of free drinking water throughout the school day, including during the meal service as required by section 9(a)(5) of the NSLA and the frequency of regular maintenance on all water fountains to ensure hygiene standards for drinking fountains, water jugs, hydration stations, water jets, and other methods for delivering drinking water.

To assist schools, the Department will develop standard statements for use by LEAs, describing the updated nutrition standards for school meals, as well as standard statements for use by those LEAs indicating the status of compliance with the updated meal patterns. These statements may be used as a part of the local school wellness policy, wellness policy assessments, and the progress reports to the public.

Nutrition standards for other foods available to students: The NSLA at section 9A(b)(2) also requires that the local school wellness policy include nutrition standards for all other foods available on campus, defined as ''competitive foods''. This would include foods and beverages that are available for sale to students, which are subject to the interim rule, *Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010* (78 FR 39068), also known as the ''Smart Snacks in School'' rule, as well as any other foods and beverages available (such as in classroom parties, classroom snacks brought by parents, or foods given as incentives) on the school campus during the school day. (For more information on Smart Snacks, refer to the Smart Snacks Web site at *http://www.fns.usda.gov/school-meals/smart-snacks-schools*).

The Federal Smart Snacks standards are minimum standards. State agencies and LEAs may adopt more stringent standards for the types of food and beverages allowed to be sold, as well as the limited frequency of fundraisers that include foods that do not meet the standards. A local school wellness policy can be an excellent tool for establishing and communicating these local standards.

The local school wellness policy could include information on the types of foods and beverages available for sale in each elementary, middle, and high school, and as appropriate and applicable, the general or specific nutrient profile of those foods and beverages, as well as a description of the Smart Snacks nutrition standards, an indication if the LEA is in compliance with the Smart Snacks nutrition standards, and policies regarding in-school fundraising activities that involve food and whether in-school fundraisers that involve food and beverages meet the Smart Snacks nutrition standards.

In addition to addressing food and beverages *sold* to students, the local school wellness policy must also address standards for other foods and beverages *available* on campus. These would include policies such as those

governing classroom parties or school celebrations that involve food, policies governing food-related rewards and incentives, and other State or local policies or nutrition standards for foods and beverages available that promote student health and reduce childhood obesity.

To assist schools in describing the Smart Snacks nutrition standards and the status of compliance with those standards, the Department will develop standard statements for use by LEAs, describing the new Smart Snacks nutrition standards, as well as standard statements for use by those LEAs indicating the status of compliance with the new Smart Snacks nutrition standards. These statements may be used as a part of the local school wellness policy, wellness policy assessments, and progress reports to the public.

Policies for Food and Beverage Marketing

As discussed above and included in the proposed rule at § 210.30(c)(1), LEAs must include goals for nutrition promotion in their local school wellness policies. One important aspect of nutrition promotion is the marketing of food and beverages on the school campus. For the purposes of this proposed rule, marketing is defined as advertising and other promotions in schools. This rule proposes to require, at § 210.30(c)(2)(iii), that LEAs include in their local wellness plans policies that allow marketing of only those foods and beverages that may be sold on the school campus during the school day, i.e., those foods and beverages that meet the requirements set forth in the Smart Snacks interim rule (or the more restrictive standards adopted by the LEA, if applicable).

Food marketing commonly includes oral, written, or graphic statements made for the purpose of promoting the sale of a food or beverage product made by the producer, manufacturer, seller, or any other entity with a commercial interest in the product.[13] Food and beverage marketing may be present in areas of the school campus that are owned or leased by the school and used at any time for school-related activities such as the school building or on the school campus, including on the outside of the school building, areas adjacent to the school building, school buses or other vehicles used to transport students, athletic fields and stadiums (e.g. on scoreboards, coolers, cups, and water bottles), or parking lots. USDA is interested in receiving public comment specifically on this proposed requirement, as discussed below, to inform the interim or final rule and help clarify how such policies would apply.

The Department is also seeking comment on the definition of food marketing, which commonly includes oral, written, or graphic statements made for the purpose of promoting the sale of a food or beverage product made by the producer, manufacturer, seller, or any other entity with a commercial interest in the product.[10]

Food and beverage marketing is prevalent in schools, and the majority of foods and beverages marketed to children are low in nutritional value and high in sugar and fat.[14] [15] Research shows that food marketing influences children's food preferences, dietary intake, and overall health.[16] However, the majority of schools do not have policies restricting food marketing to children. During the 2010–2011 School Year, only 10% of school districts nationwide had a strong policy restricting the marketing of unhealthy foods, where strong policy provisions were defined as those that required action, specified an implementation plan or strategy, and included language such as shall, must, require, comply, and enforce.[17] The 2012 School Health Policies and Practices Study noted that 38% of districts nationwide required and 28% recommended that schools prohibit advertisements for unhealthy foods and fast food restaurants (representing over 8,400 school districts). In addition, 32% of districts required and 26% recommended that schools prohibit the distribution of products promoting unhealthy foods and fast food restaurants.[18] Research has found that the financial impact on schools of prohibiting food marketing in schools would not likely be significant. In 2009, industry spent approximately $149 million on marketing in schools, with 93% of the funds spent on the marketing of beverages.[19] However, school officials noted that they receive little financial compensation from corporate advertisements, with 67% of school officials reporting no compensation. In addition, 88% of school officials noted that school programs and activities would not be reduced if advertisements of unhealthy food ceased.[20] A study of five large school districts noted that yearly revenues from corporate advertising represented, on average, 0.01% of the schools' yearly operating budgets.[21]

The marketing of products on the exterior of vending machines, through posters, menu boards, coolers, trash cans, and other food service equipment, as well as cups used for beverage dispensing would all be subject to these policies. These policies would not apply to marketing that occurs at events outside of school hours such as after school sporting or other events, but they could at the LEA's discretion. For example, it is not the intent of the Department that an existing scoreboard on a field be replaced to comply with this proposal. However, LEAs are encouraged to consider that, as a scoreboard or other such durable equipment is replaced or updated over time, decisions about the replacement include compliance with the marketing policy.

This proposal is also not intended to establish limits on personal expression

[13] National Policy & Legal Analysis Network to Prevent Childhood Obesity. District Policy Restricting Food and Beverage Advertising on School Grounds. Available from: *http://changelabsolutions.org/publications/district-policy-school-food-ads.*

[14] California Project LEAN. *Food and Beverage Marketing on California High School Campuses Survey: Findings and Recommendations.* California: Project LEAN, 2006. Available from: *http://californiaprojectlean.org/doc.asp?id=174&parentid=20.*

[15] Molnar A, Garcia DR, Boninger F, Merrill B. A *National Survey of the Types and Extent of the Marketing of Foods of Minimal Nutritional Value in Schools.* Tempe, AZ: Commercialism in Research Unit, 2006. Available from: *http://nepc.colorado.edu/publication/national-survey-types-and-extent-marketing-foods-minimal-nutritional-value-schools.*

[16] Institute of Medicine. *Food Marketing to Children: Threat or Opportunity?* Washington, DC: National Academies Press, 2005. Available from: *http://www.iom.edu/~/media/Files/Report%20Files/2005/Food-Marketing-to-Children-and-Youth-Threat-or-Opportunity/KFMOverviewfinal2906.pdf.*

[17] Chriqui JF, Resnick EA, Schneider L, Schermbeck R, Adcock T, Carrion V,Chaloupka FJ. *School District Wellness Policies: Evaluating Progress and Potential for Improving Children's Health Five Years after the Federal Mandate. School Years 2006–07 through 2010–11.* Volume 3. Chicago, IL: Bridging the Gap Program, Health Policy Center, Institute for Health Research and Policy, University of Illinois at Chicago, 2013. Available from: *http://www.bridgingthegapresearch.org/research/district_wellness_policies/.*

[18] Centers for Disease Control and Prevention. *Results from the School Health Policies and Practices Study 2012,* 2013. Available from: *http://www.cdc.gov/healthyyouth/shpps/2012/pdf/shpps-results_2012.pdf#page=81.*

[19] Federal Trade Commission. *A Review of Food Marketing to Children and Adolescents,* 2012. Available from: *http://ftc.gov/os/2012/12/121221foodmarketingreport.pdf.*

[20] Molnar A, Garcia DR, Boninger F, Merrill B. A *National Survey of the Types and Extent of the Marketing of Foods of Minimal Nutritional Value in Schools.* Tempe, AZ: Commercialism in Research Unit, 2006. Available from: *http://nepc.colorado.edu/publication/national-survey-types-and-extent-marketing-foods-minimal-nutritional-value-schools.*

[21] Public Citizen. School Commercialism: High Costs, Low Revenues, 2012. Available from: *http://www.commercialalert.org/PDFs/SchoolCommercialismReport_PC.pdf.*

or opinions. For example, it is not intended that this proposal would apply to clothing or personal items used by students or staff, or the packaging of products brought from home for personal consumption. It is also not intended to apply to materials used for educational purposes in the classroom, such as teachers' use of soda advertisements as a media education tool, nor would a LEA be limited in implementing a health or nutrition education curriculum that favors the consumption of some foods over others (for example, a curriculum that favors the consumption of dairy vs. dairy-free alternatives, or one that favors a vegetarian diet vs. animal protein foods). It is also not intended to imply that schools must allow food or beverage marketing on campus.

In developing this aspect of the proposed rule, the Department conducted a review of published data and research on food and beverage marketing in schools, including some publications that synthesize recent findings on the types of food and beverage policies being adopted, their feasibility, and their impact. The extent of peer-reviewed research in these areas is relatively limited. To ensure all relevant and reliable information available is considered in formulating an interim or final rule on local school wellness policies, the Department invites the public to submit research findings and other descriptive data related to food and beverage advertising or marketing on the school campus during the school day via product sales (e.g., via exclusive contracts, corporate food vending and associated incentives and profits, cash and rebate programs, and fundraising), direct advertising (in school facilities, school buses, school publications, media-based advertising on in-school televisions and radio, food coupons as incentives), indirect advertising (via corporate sponsored educational materials, teacher training, contests and incentives, grants, gifts, or event sponsorships), and market research (via surveys, internet panels, or internet tracking).

The Department is also seeking information on the current food and beverage marketing environment in schools, as well as information on the fiscal implications for LEAs or schools that have implemented policies regulating the marketing of foods and beverages in schools; the effects of food and beverage marketing on student health, behavior, and academic performance; as well as data on actual and anticipated impacts of limiting school-based food marketing to foods permitted to be sold on the school campus during the school day. Specifically, the Department seeks information on:

—The extent to which food and beverage marketing practices in schools differ by school level (i.e. elementary, middle, and high school);
—The number and/or percentage of schools that currently allow (and/or that currently prohibit, or otherwise restrict) food and beverage marketing in the school and on the school campus: (1) during the school day, and/or (2) at all times;
—The types of food and beverages currently being marketed in school and the extent to which they meet or do not meet the ''Smart Snacks in School'' nutrition standards;
—The impact of food and beverage marketing on student health, behavior, food choices, food consumption patterns, and academic performance;
—The role of food and beverage marketing on school finances, including its contribution to school food service revenue and overall school revenues;
—The reliance of students, parents, teachers, school staff, and other school-affiliated groups on revenue or donations from product sales, direct advertising, indirect advertising, and market research;
—The extent to which such food and beverage marketing policies could apply to broadcast media conducted by or used in schools, including media used by schools for educational purposes that may be provided by outside entities;
—The use of in-kind rewards, such as coupons from restaurants for children reading a certain number of books, or other donations for student rewards, and the wellness impacts of these in-kind rewards.
—The economic and other impacts of existing State, local, and voluntary policies on allowing marketing only of foods and beverages permitted to be sold on the school campus (as per the Smart Snacks standards, or more stringent competitive foods standards adopted by the school) on the private sector, including, but not limited to, food producers/manufacturers, distributors, and vendors;
—Recently enacted or updated State or local level policies on allowing marketing of food and beverages permitted to be sold on the school campus, their immediate effects on student demand for competitive foods and reimbursable meals and the anticipated long-term effects on school revenue and revenue raised by school-affiliated groups;
—Strategies that have been utilized to implement existing State, local, and voluntary policies that restrict food and beverage marketing, including:
○ Strategies for mitigating potential adverse financial impacts;
○ Strategies for handling prohibited or restricted marketing and exclusive contracts that already exist in schools (e.g. what schools have done about existing scoreboards, signage, or vending machines advertising foods not allowed to be sold on the school campus);
○ Strategies for marketing or displaying company brands, names, logos, or mascots that have some products that meet ''Smart Snacks'' standards and some products that do not;
○ Details on the specific locations within the school campus where food marketing is present (e.g. in the school building, exterior of school building, areas adjacent to school building, school buses or other vehicles that transport students, athletic fields and stadiums, and parking lots).
—Community and consumer understanding of the impact of the role of food and beverage marketing in schools on children's diet and health; and
—Issues associated with compliance and monitoring of existing State and local policies regarding the marketing of food and beverages permitted to be sold on the school campus (as per the ''Smart Snacks'' standards).

Informing the Public

Section 9A(b)(4) of the NSLA, as amended, requires the LEA to inform and update the public (including parents, students, and others in the community) about the content and implementation of the local school wellness policy.

Under proposed § 210.30(d)(2), LEAs would be required to inform the public about the content of the local school wellness policy and make the local school wellness policy and any updates to the policy available to the public on an annual basis, at a minimum. In addition to the local school wellness policy, the LEA would be required to make readily available to the public the annual school progress reports and triennial assessments of the local school wellness policy which are discussed in more detail later in this preamble.

LEAs or schools would be required to actively notify households of the availability of the local school wellness policy information, the Web site address (i.e., URL or uniform resource locator) for the information, or other information that would enable interested households

to obtain additional information. For example, LEAs could post the local school wellness policy on the school or LEA's Web site and send a message to families notifying them of how they may obtain a copy or otherwise access the policy. Also, as a follow-up to the online posting, the LEA could publicize the content and status of the local school wellness policy by sending a summary report directly home to parents, and could present the information during a meeting with the Parent Teacher Association/Organization, school board, district superintendent, school/district health and wellness committee, school health advisory council, or other interested groups or stakeholders. Other examples of methods for public information sharing with the larger community include notifications through local newspapers or the media, with links to a Web page on the school or LEA's Web site.

Section 209 of the HHFKA amended the NSLA to require USDA to establish requirements for LEAs to report information on the school nutrition environment to the public on a periodic basis, including information pertaining to food safety inspections, meal program participation, the nutritional quality of school meals, and other information. This new requirement complements the public notification requirements set forth in this proposed rule. USDA will address section 209 through a separate proposed rulemaking in the future. Prior to that rulemaking, USDA strongly encourages LEAs to provide as much information as possible to their communities about the school nutrition environment.

Implementation, Assessment, and Updates

Annual Progress Reports

Sections 9A(b)(4) and 9A(b)(5) of the NSLA, as amended, require the LEA to inform and update the public about the content and implementation of the local school wellness policy, the extent to which schools are in compliance with the policy, and progress made in attaining the goals of the policy. The intent of these requirements is to promote public transparency and ensure parents have easy access to information about the wellness environment of the school their child attends. In developing the proposal, the Department felt it was important to balance the need to inform parents and the community about the implementation of the local school wellness policy with the potential burden of assessing compliance, particularly for LEAs with a large number of schools.

Therefore, this rule proposes, at § 210.30(e)(2), that LEAs inform parents and the public each school year of basic information about the local school wellness policy, the progress of each school toward meeting the goals of the policy, and any activities related to the policy that the school conducts. The timing of the notification each year is left to the discretion of the LEA, though it is recommended it occur early in the school year. The local school wellness policy annual progress report must include, at a minimum:

- The Web site address (i.e., URL or uniform resource locator) for the local school wellness policy and/or how the public can receive/access a copy of the local school wellness policy;
- A description of each school's progress in meeting the local school wellness goals;
- A summary of each school's events or activities related to local school wellness policy implementation;
- The name, position title, and contact information of the designated local agency official(s) or school official(s) leading/coordinating the school wellness policy team/health advisory council; and
- Information on how individuals and the public can get involved with the school wellness policy team.

The progress report can be written in any format that the LEA chooses, so long as it is written in an accessible and easily understood manner and covers the required elements. LEAs and schools may use any of the aforementioned standard phrases/statements developed by the Department to describe the extent to which schools are in compliance with the local school wellness policy in their assessments and progress reports made available to the public. One way to meet this annual progress reporting requirement is to create a ''school wellness report card'' that details a school or LEA's progress in various areas in support of the local school wellness policy, which could be folded into other annual school/district/LEA report card-type ratings that are available to the public.

This rule proposes to require the progress report to be completed and made available to the public every year, at a minimum. However, LEAs can choose to report the progress of their policies more frequently to communicate school-based wellness activities, events, and opportunities to families and the community. Commenters are encouraged to address whether the annual frequency of the progress reporting would serve to ensure local school wellness policies and school-based activities are communicated to parents and the community without being overly burdensome to LEAs.

The LEA may prepare and make the local school wellness policy progress report available on behalf of each participating school under its jurisdiction, or may allow each school to prepare its own progress report and make the information available to the public. The information may be posted on the LEA or schools' Web site, however, each year the LEA or school must actively notify households of the availability of the information, the Web site address (i.e., URL or uniform resource locator) for the information, or other information that would enable households to obtain additional information.

Triennial Assessments

Section 9A(b)(5) of the NSLA, as amended, requires LEAs to periodically measure and make available to the public an assessment on the implementation of the local school wellness policy, including:

- An indication of the extent to which schools under the jurisdiction of the LEA are in compliance with the local school wellness policy;
- An indication of the extent to which the local school wellness policy compares to model local school wellness policies; and
- A description of the progress made in attaining the goals of the local school wellness policy.

This rule proposes, at § 210.30(e)(3), to require an assessment, as described above, of the local school wellness policy to be conducted, at a minimum, every 3 years. However, LEAs can choose to assess their policies more frequently to ensure goals and objectives are being met and to refine the policy as needed. The results of this periodic assessment must be made available to the public to showcase the wellness efforts being made by the LEA. Commenters are encouraged to address whether the 3-year frequency of the assessment would serve to ensure local school wellness policies are kept up-to-date without being overly burdensome to LEAs.

There are a variety of methods an LEA may employ to assess compliance by schools and determine progress toward benchmarks, objectives and goals. Developing a plan with measureable objectives, and realistic annual benchmarks will help when it is time to evaluate progress. Additionally, the local school wellness policy team and

leadership can be assets in conducting periodic assessments. Commenters are encouraged to provide input on the specific areas that should be included in the components of an effective assessment. The Department will continue to work with the Department of Education and the Department of Health and Human Services to identify resources and provide technical assistance on this area.

Updates

Section 9A(b)(3) of NSLA, as amended, requires that LEAs periodically update the local school wellness policy. As community needs change, as goals are met and as new health science, information, and technology emerge, it is important for LEAs assess the local school wellness policy and update as appropriate. The proposed rule at § 210.30(e)(4) requires that LEAs update or modify the local school wellness policy as appropriate, particularly as information is gathered through the annual progress reports or triennial assessments. The frequency of updates to the local school wellness policy is not specified, as the need to update will vary based on the content and structure of the plan. For example, a comprehensive plan that establishes benchmarks toward a measurable goal over the course of several years may not need frequent updates, while other plans may need to be revisited more frequently. The local school wellness policy team and leadership can be assets in determining when updates are needed.

Recordkeeping

The proposed rule at § 210.30(f) would require each LEA to retain basic records demonstrating compliance with the local school wellness requirements set forth under § 210.30. In order to minimize burden, the records required to be retained would include:

- The written local school wellness policy;
- Documentation demonstrating compliance with community involvement requirements;
- Documentation of the triennial assessment of the local school wellness policy;
- Annual local school wellness policy progress reports for each school under its jurisdiction; and
- Documentation to demonstrate compliance with the public notification requirements (consistent with the section on *Informing the public*).

Monitoring and Oversight

State agencies conduct administrative reviews of LEAs, at least once every three years. The proposed rule at § 210.18(h)(6) would require State agencies to include, as part of the general areas of the administrative review, compliance with the local school wellness policy requirements set forth under proposed § 210.30, *Local school wellness policy.* Information on the content of the review and methods States can use to assess compliance will be provided within the School Meals Administrative Review guidance.

Technical Assistance and Best Practices

In addition to describing requirements of LEAs for the local school wellness policy, section 9A of the NSLA, requires USDA, in consultation with the Department of Education and the Centers for Disease Control and Prevention of the Department of Health and Human Services, to provide information and technical assistance to LEAs, school food authorities and State agencies to support local school wellness policies. The law specifies several types of technical assistance that USDA must provide, including resources and training, model school wellness policies and best practices, and other technical assistance that promotes sound nutrition and healthy school environments and is consistent with the specific needs of LEAs. In April 2011, the Food and Nutrition Service, Department of Education, and Centers for Disease Control convened an interagency workgroup and conducted several needs assessment activities to help determine the training and technical needs of LEAs. Based on this assessment the workgroup developed a five-year technical assistance plan. The workgroup is prepared to identify best practices and success stories for local school wellness policy implementation as well as other technical assistance resources that will support LEAs in developing, updating and assessing their policies.

In order to assist LEAs in implementing these requirements, the Department will continue to provide technical assistance. The Team Nutrition Web site hosts resources on designing, implementing, promoting, disseminating, and evaluating local school wellness policies and overcoming barriers to the adoption of local school wellness policies. For more information, refer to *http://teamnutrition.usda.gov/healthy/wellnesspolicy.html.*

The ''School Nutrition Environment and Wellness Resources'' Web site, operated by USDA National Agricultural Library's Healthy Meals Resource System (Team Nutrition's training and technical assistance component), helps LEAs find the resources they need to meet the local school wellness policy requirements and recommendations to establish a healthier school nutrition environment (http://healthymeals.nal.usda.gov/school-wellness-resources). The ''School Nutrition Environment and Wellness Resources'' Web site has information and resources on:

- Local School Wellness Policy Process steps to put the policy into action.
- Required Wellness Policy Elements to meet the federal requirements.
- Healthy School Nutrition Environment improvements related to food and physical activity.
- Samples, Stories, and Guidance ideas for schools.
- Research Reports on school wellness.
- Grants and funding opportunities related to child nutrition and physical activity.

FNS will continue to identify, develop, and post to the Team Nutrition and ''School Nutrition Environment and Wellness Resources'' Web sites model local school wellness policies that will help local educational agencies assess the extent to which the local school wellness policy compares to model local school wellness policies, as required under the triennial assessment, as well as best practices and any other technical assistance as needed to develop, implement, assess, and report on local school wellness policies that promote healthy school nutrition environments.

II. Procedural Matters

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule has been determined to be significant under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act Summary

This rule has been reviewed with regard to the requirements of the

Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612). It has been certified that this rule will have a significant impact on a substantial number of small entities. A summary is presented below. The complete RFA is included in the docket for this rule at *www.regulations.gov* (docket #FNS–2014–0010).

The requirements established by this proposed rule will apply to LEAs which meet the definitions of ''small governmental jurisdiction'' and ''small entity'' in the Regulatory Flexibility Act. The regulatory flexibility analysis considers the impact of the proposed rule on small businesses. The proposed rule has the potential to affect approximately 21,000 local educational agencies and some 105,000 schools operating in the U.S. We estimate that the administrative cost for schools will be on average about $48 per school per year. The marketing limitations in the proposed rule could affect vending machine operators and marketing companies as they change existing marketing to meet the requirements. Because of the changes in products available in schools due to the Smart Snacks in Schools interim rule, we believe that much of that change will already have occurred, but there may still be some labor costs associated with changing the marketing campaigns.

Regulatory Impact Analysis Summary

As required for all rules that have been designated significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this proposal. A summary is presented below. The complete RIA is included in the docket for this rule at *www.regulations.gov.* The docket number is FNS–2014–0010.

Need for Action

The proposed rule updates the regulations governing the administration of USDA's child nutrition programs in response to statutory changes made by The Healthy, Hunger-Free Kids Act of 2010.[22] Section 204 of the Healthy, Hunger-Free Kids Act of 2010 added section (9A) to the Richard B. Russell National School Lunch Act. This new section requires local educational agencies (LEAs) to establish more comprehensive local wellness policies and expands the scope of existing wellness policies; brings additional stakeholders into the development, implementation, and review of local school wellness policies; and requires public updates on the content and implementation of the wellness policies.

Benefits

The proposed rule adds to the scope of existing wellness policies and provides guidelines for local educational agencies and the Department regarding their roles in these policies, as required by the Healthy, Hunger-Free Kids Act of 2010.

As documented in the Bridging the Gap study,[23] there is substantial variability in local wellness policies, in the strength of those policies, and in policy enforcement, meaning that not all school children are benefitting from the policies in their schools.

The proposed rule strengthens the requirements for the local wellness policies and puts more emphasis on policy implementation. Under the proposed rule, LEAs and schools are encouraged to identify specific, measurable objectives with attention to both long- and short-term goals. The wellness committee responsibilities have also been expanded to include oversight on policy implementation. LEAs must now designate at least one LEA official to be responsible for periodically determining the extent to which schools are in compliance with their wellness policies and the extent to which the policy compares with model policy.

The proposed rule also includes a provision that allows schools to permit in-school marketing of only those foods and beverages that meet the standards in the Smart Snacks in Schools interim rule. The new marketing rules will mean that children are presented with images and signs that promote healthier foods and beverages and that the products that are marketed will match the foods and beverages that will be available in schools.

Under the proposed rule, schools must also inform and update the public about the content of their policies and the status of policy implementation. LEAs must also formally assess their policies to ensure that goals and objectives are being met. With greater transparency on the effectiveness of these policies, parents and other community stakeholders will be better informed and positioned to improve the school nutrition and wellness environment.

As noted in the Bridging the Gap study, strong evidence is emerging that demonstrates the links between healthy nutrition, physical activity, improved academic performance, and improved classroom behavior.[24] For example Rampey, Dion, and Donahue (2008) found that children who are more physically fit are more likely to perform better on reading and math tests, even if the additional time for physical activity decreases the time available for classroom instruction.[25] Similar outcomes have been found in Texas among students in grades 3–12, among Massachusetts middle school students, and among Illinois 3rd and 5th graders.[26] The Bridging the Gap study also notes that there is increasing evidence showing that ''school-based policies regarding foods, beverages, and physical activity are significantly related to calories consumed and expended by school age children, and to their weight and body mass index levels.'' [27] Therefore, there is a high likelihood that strengthening local wellness policies will have real positive effects on the health outcomes for students, though these benefits cannot be quantified nationally with precision using existing data.

Finally, the rule requires LEAs to give increased attention to their implementation of the new school meal pattern requirements and the Smart Snacks in Schools requirements. As described in the regulatory impact analysis published with the school meals rule,[28] the benefits of the new school meal pattern requirements include improved nutrition and diets to students and likely improved health outcomes. Furthermore, as described in the regulatory impact analysis published with the Smart Snacks in Schools rule,[29] the benefits of the Smart Snacks in Schools rule likely include decreased consumption of solid fats and added sugars and decreased obesity rates.

Although we do not estimate new direct benefits in these areas from this proposed rule, we expect that the

[22] Public Law 111–296.

[23] Chriqui JF, Resnick EA, Schneider L, Schermbeck R, Adcock T, Carrion V, Chaloupka FJ. *School District Wellness Policies: Evaluating Progress and Potential for Improving Children's Health Five Years After the Federal Mandate. School Years 2006–07 Through 2010–11.* Volume 3. Chicago, IL: Bridging the Gap Program, Health Policy Center, Institute for Health Research and Policy, University of Illinois at Chicago, 2013, *www.bridgingthegapresearch.org.*

[24] Chriqui et al., 2013, p. 4.

[25] Rampey, B, Dion, G and Donahue, P., *NAEP 2008 Trends in Academic Progress,* Washington, DC: U.S. Department of Education, 2008.

[26] Troust, SG, Active Living Research, ''Active education: Physical Education, Physical Activity, and Academic Performance.'' Available online at *http://activelivingresearch.org/files/ALR_Brief_ActiveEducation_Summer2009.pdf.*

[27] Chriqui et al., 2013, p. 4.

[28] **Federal Register**, Vol. 77, No. 17, pp. 4088–4167.

[29] **Federal Register**, Vol. 78, No. 125, pp. 39068–39120.

consistent reinforcing influence of local wellness policies will likely cause a number of LEAs to reexamine and improve their implementation of both the school meals rule and the Smart Snacks rule. To the extent that this proposed rule causes LEAs to implement the school meals rule or Smart Snacks rule more quickly or with more stringent requirements, this rule could cause LEAs to realize the benefits of those rules more quickly or to a greater extent than they might have done in the absence of this proposed rule.

Costs/Administrative Impact

There are no transfers as a result of this rule, and we estimate that there is no quantifiable economic impact beyond the new public disclosure and recordkeeping requirements for LEAs established as a result of this rule. LEAs will face increased public disclosure and recordkeeping burdens in order to establish and implement the policies, conduct annual and triennial assessments of wellness policies, track policy implementation, and retain documentation of these assessments. We estimate these costs to be approximately $5 million per year across the entire United States. A summary table of the estimated costs of the proposed rule is provided below.

RECORD AND REPORTING REQUIREMENT COSTS FOR LOCAL SCHOOL WELLNESS POLICIES

Administrative burden on LEAs	Fiscal year (millions)					
	2014	2015	2016	2017	2018	Total
Additional Public Disclosure Burden on LEAs						
Each LEA must establish a local wellness policy for all participating schools	$2.64	$2.73	$2.82	$2.92	$3.01	$14.13
LEAs are required to report schools annual progress towards meeting wellness policy goals, objectives, and benchmarks; make report available to public	1.32	1.37	1.41	1.46	1.51	7.06
LEAs are required to conduct triennial assessments; make results available to public; and make updates and modifications to policies as needed	0.09	0.09	0.09	0.10	0.10	0.47
Total Estimated Public Disclosure Burden	4.06	4.19	4.33	4.47	4.62	21.66
Additional Recordkeeping Burden on LEAs						
LEAs must retain records demonstrating compliance with the local school wellness requirements	0.66	0.68	0.71	0.73	0.75	3.53
Total Additional Administrative Burden on LEAs	4.72	4.87	5.03	5.20	5.37	25.19

*The BLS, FY2012 employer cost for State and local government public administration employee wage rate is used in this estimate and inflated on a fiscal year basis by the State and Local Expenditure Index used and prepared by OMB for use in developing the President's FY 2014 President's Budget.

We request comments on the costs discussed above, specifically for information to better inform their estimation. Ongoing technical assistance for local school wellness policies has been provided by FNS since 2004, therefore,—there will be minimal impact for FNS.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''Federal mandates'' ' that may result in expenditures by State, local or tribal governments, in the aggregate, or the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This proposed rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments or the private sector of $100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The National School Lunch Program is listed in the Catalog of Federal Domestic Assistance Programs under 10.555. For the reasons set forth in the final rule in 7 CFR part 3015, subpart V, and related Notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Executive Order 13132

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132. USDA has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. This rule does not impose substantial or direct compliance costs on State and local governments. Therefore, under Section 6(b) of the Executive Order, a federalism summary impact statement is not required.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect unless so specified in the Effective Dates section of the final rule. Prior to any

judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this proposed rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis'', and 1512–1, ''Regulatory Decision Making Requirements'' to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, FNS has determined that this rule is not intended to limit or reduce in any way the ability of protected classes of individuals to receive benefits on the basis of their race, color, national origin, sex, age or disability, nor is it intended to have a differential impact on minority-owned or -operated business establishments, and women-owned or -operated business establishments that participate in the Child Nutrition Programs. The proposed rule affects only the State agencies and the LEAs, requiring the establishment of local school wellness policies, assessment of those policies, and establishment of a means to communicate information related to local school wellness policies to households of all children.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320), requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current, valid OMB control number. This is a new collection. The proposed provisions in this rule create new burden which will be merged into a currently approved information collection titled ''National School Lunch Program'' (NSLP), OMB Number 0584–0006 which expires on February 29, 2016. These changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995. When the information collection requirements have been approved, FNS will publish a separate action in the **Federal Register** announcing OMB's approval.

Comments on the information collection in this proposed rule must be received by April 28, 2014. Send comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC 20503. Please also send a copy of your comments to Lynn Rodgers, Chief, Program Monitoring Branch, Child Nutrition Programs, 3101 Park Center Drive, Alexandria, VA 22302. For further information, or for copies of the information collection requirements, please contact Lynn Rodgers at the address indicated above. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the Agency's functions, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the proposed information collection 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 use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this request for comments will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: Local School Wellness Policy Implementation under the Healthy, Hunger-Free Kids Act of 2010

OMB Number: 0584–New.

Expiration Date: Not Yet Determined.

Type of Request: New Collection.

This proposed rule would increase the recordkeeping and public disclosure burden for local educational agencies. As the State agencies conduct administrative reviews of local education agencies once every three years, burden associated with local wellness policy implementation is captured as a part of administrative review process. Hence, no new burden is assessed for State agencies as a part of this proposed rule. The average burden per response and the annual burden hours are explained and summarized below.

Affected Public: Local Educational Agencies.

Estimated Number of Respondents: 20,858.

Estimated Number of Responses per Respondent: 15.3333.

Estimated Total Annual Responses: 319,822.

Estimate Time per Response: 0.7554.

Estimated Total Annual Burden: 241,604.5.

Refer to the table below for estimated total annual burden.

Affected public	Section	Estimated number of respondents	Number of responses per respondent	Total annual responses *	Estimated total hours per response	Estimated total burden hours
Public Disclosure						
Each LEA must establish a local wellness policy for all participating schools.	210.30(a)	20,858	5	104,290	1.0	104,290
LEAs are required to report schools' annual progress towards meeting wellness policy goals; make report available to public.	210.30(e)(2), (d)(2), & (d)(3).	20,858	5	104,290	1.0	104,290
LEAs are required to conduct triennial assessments; make results available to public; and make updates and modifications to policies as needed.	210.30(e)(3), (d)(3), & (e)(4).	6,952	1	6,952	1.0	6,952
Total Estimated Public Disclosure Burden	.....	20,858	10.3333	215,532	1.0	215,532
Recordkeeping						
LEAs must retain records demonstrating compliance with the local school wellness requirements.	210.30(f)	20,858	5	104,290	0.25	26,072.5

Affected public	Section	Estimated number of respondents	Number of responses per respondent	Total annual responses *	Estimated total hours per response	Estimated total burden hours
Total Estimated Recordkeeping Burden		20,858	5	104,290	0.25	26,072.5
Total of Public Disclosure and Recordkeeping for Local School Wellness Policies						
Public Disclosure		20,858	10.3333	215,532	1.0	215,532
Recordkeeping		20,858	5	104,290	0.25	26,072.5
Total		20,858	15.33	319,822	.75	241,604.5

* The Number of Responses per Respondent reflects a rounded average of the number of participating schools split among the number of LEAs. As such, the Total Annual Responses figure is higher than the actual number of participating schools.

E-Government Act Compliance

The Food and Nutrition Service is committed to complying with the E-Government Act, 2002 to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes. In spring 2011, FNS offered five opportunities for consultation with Tribal officials or their designees to discuss the impact of the Healthy, Hunger-Free Kids Act of 2010 on tribes or Indian Tribal governments. FNS followed up with conference calls on February 13, 2013; May 22, 2013; August 21, 3013; and November 6, 2013. These consultation sessions have provided and will continue to provide the opportunity to address Tribal concerns related to school meals. No concerns about the local school wellness policy have been expressed by the Indian Tribal governments.

The impact of this proposed rule on Tribal members is expected to be positive. The rule expands the scope of wellness policies; brings in additional stakeholders in the development, implementation, and review of local school wellness policies; and requires public updates on the content and implementation of the wellness policies. The local school wellness policies would support Tribal efforts to reduce obesity and diabetes in their communities by providing a school environment that promotes sound nutrition and student health, reduces childhood obesity, provides transparency to the public on school wellness policy content and implementation, and promotes healthy eating and physical activities through campaigns such as *Let's Move in Indian Country.*

USDA will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences with Tribal officials or their designees concerning ways to improve this rule in Indian country. We are unaware of any current Tribal laws that would be in conflict with the proposed rule. We request that commenters address any concerns in this regard in their responses.

List of Subjects

7 CFR 210

Grant programs—education; Grant programs—health; Infants and children; Nutrition; Reporting and recordkeeping requirements; School breakfast and lunch programs.

7 CFR 220

Grant programs—education; Grant programs—health; Infants and children; Nutrition; Reporting and recordkeeping requirements; School breakfast and lunch programs.

Accordingly, 7 CFR parts 210 and 220 are proposed to be amended as follows:

PART 210—NATIONAL SCHOOL LUNCH ACT

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

■ 2. In § 210.12, revise the section heading and add new paragraph (e) to read as follows:

§ 210.12 Student, parent, and community involvement.

* * * * *

(e) *Local school wellness policies.* Local educational agencies must comply with the provisions of § 210.30(c) regarding student, parent, and community involvement in the development, implementation, and periodic review and update of the local school wellness policy. Additionally, local educational agencies must make information about the content and implementation of the local school wellness policy available to the public, as required under § 210.30(c).

■ 3. In § 210.15, add new paragraph (b)(8) to read as follows:

§ 210.15 Reporting and recordkeeping.

* * * * *

(b) * * *

(8) Records to document compliance with the local school wellness policy requirements as set forth in § 210.30(h).

■ 4. In § 210.18, add new paragraph (h)(7) to read as follows:

§ 210.18 Administrative reviews.

* * * * *

(h) * * *

(7) *Local school wellness.* The State agency shall ensure the school food authority complies with the local school wellness requirements set forth in § 210.30.

§§ 210.30 and 210.31 [Redesignated as §§ 210.31 and 210.32]

■ 5. Redesignate § 210.30 and § 210.31 as § 210.31 and § 210.32, respectively.

■ 6. Add new § 210.30 to read as follows:

§ 210.30 Local school wellness policy.

(a) *General.* Each local educational agency must establish a local school wellness policy for all schools participating in the National School Lunch Program and/or School Breakfast Program under the jurisdiction of the local educational agency. The local school wellness policy is a written plan that includes methods to promote

student wellness, prevent and reduce childhood obesity, and provide assurance that school meals and other food and beverages sold on the school campus during the school day meet the minimum Federal standards.

(b) *Definitions.* For the purposes of this section:

(1) *School campus* means the term as defined in § 210.11(a)(4).

(2) *School day* means the term as defined in § 210.11(a)(5).

(c) *Content of the plan.* At a minimum, local school wellness policies must contain:

(1) Specific goals for nutrition promotion and education, physical activity, and other school-based activities that promote student wellness. In developing these goals, local educational agencies must review and consider evidence based strategies and techniques;

(2) Standards and nutrition guidelines for all foods and beverages available during the school day on each participating school campus under the jurisdiction of the local educational agency that:

(i) Are consistent with the meal pattern requirements set forth under §§ 210.10 and 220.8 of this chapter, as applicable;

(ii) Are consistent with the nutrition standards set forth under § 210.11;

(iii) Permit marketing on the school campus during the school day of only those foods and beverages that meet the requirements under § 210.11; and

(iv) Promote student health and reduce childhood obesity.

(3) Identification of the position of the LEA official(s) or school official(s) responsible for the oversight of the local school wellness policy to ensure each school's compliance with the policy;

(4) A description of the manner in which parents, students, representatives of the school food authority, teachers of physical education, school health professions, the school board, school administrators, and the general public are provided an opportunity to participate in the development, implementation, and periodic review and update of the local school wellness policy; and

(5) A description of the plan for measuring the implementation of the local school wellness policy and for reporting local school wellness policy content and implementation issues to the public, as required in paragraphs (d) and (e) of this section.

(d) *Community involvement.* Each local educational agency must:

(1) Permit parents, students, representatives of the school food authority, teachers of physical education, school health professionals, the school board, school administrators, and the general public to participate in the development, implementation, and periodic review and update of the local school wellness policy.

(2) Inform the public about the content of the local school wellness policy and make the local school wellness policy and any updates to the policy available to the public on an annual basis.

(3) Inform the public about progress toward meeting the goals of the local school wellness policy and compliance with the local school wellness policy by making the annual report, as required in paragraph (e)(2) of this section, and the triennial assessment, as required in paragraph (e)(3) of this section, available to the public in an accessible and easily understood manner.

(e) *Implementation, assessments and updates.* Each local educational agency must:

(1) Designate 1 or more local educational agency officials or school officials to ensure that each participating school complies with the local school wellness policy.

(2) Annually report, for each school under the jurisdiction of the local educational agency, the school's progress toward meeting the local school wellness policy's goals over the previous school year and include:

(i) The Web site address (i.e., URL or uniform resource locator) for the local school wellness policy and/or how the public can receive/access a copy of the local school wellness policy;

(ii) A description of each school's progress in meeting the local school wellness goals;

(iii) A summary of each school's events or activities related to local school wellness policy implementation;

(iv) The name, position title, and contact information of the designated local agency official(s) or school official(s) leading/coordinating the school wellness policy team/health advisory council; and

(v) Information on how individuals and the public can get involved with the school wellness policy team.

(3) At least once every three years, assess compliance with the local school wellness policy. The assessment must measure the implementation of the local school wellness policy, and include:

(i) The extent to which schools under the jurisdiction of the local educational agency are in compliance with their local school wellness policy;

(ii) The extent to which the local educational agency's local school wellness policy compares to model local school wellness policies; and

(iii) A description of the progress made in attaining the goals of the local school wellness policy.

(4) Make appropriate updates or modifications to the local school wellness policy, based on the triennial assessment and annual progress reports.

(f) *Recordkeeping requirement.* Each local educational agency must retain records to document compliance with the requirements of this section. These records include but are not limited to:

(1) The written local school wellness policy;

(2) Documentation demonstrating compliance with community involvement requirements, including requirements to make the local school wellness policy, annual progress reports, and triennial assessments available to the public as required in paragraph (d) of this section;

(3) Documentation of the triennial assessment of the local school wellness policy for each school under its jurisdiction; and

(4) Documentation of annual local school wellness policy progress reports for each school under its jurisdiction.

PART 220—SCHOOL BREAKFAST PROGRAM

■ 7. The authority citation for part 220 continues to read as follows:

Authority: 42 U.S.C. 1773, 1779, unless otherwise noted.

■ 8. In § 220.7, add paragraph (h) to read as follows:

§ 220.7 Requirements for participation.

* * * * *

(h) Local educational agencies must comply with the provisions of § 210.30 of this chapter regarding the development, implementation and periodic review and update of the local school wellness policy.

Dated: February 20, 2014.

Janey Thornton,

Acting Under Secretary, Food, Nutrition and Consumer Services.

[FR Doc. 2014–04100 Filed 2–25–14; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0058; Directorate Identifier 2013–NM–116–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede airworthiness directive (AD) 94–12–03 that applies to certain Airbus Model A320 series airplanes. AD 94–12–03 requires modification of the belly fairing structure. Since we issued AD 94–12–03, fatigue testing of Model A320 series airplanes showed cracks at the lower riveting of the four titanium angles that connect the belly fairing to the keel beam side panels on both sides of the fuselage. This proposed AD also would require repetitive inspections for cracking of the four titanium angles between the belly fairing and the keel beam side panel, an inspection for cracking of the open holes if any cracking is found, and repair or replacement if necessary. This proposed AD would also expand the applicability of AD 94–12–03. We are proposing this AD to detect and correct cracking of the titanium angles that connect the belly fairing to the keel beam side panels on both sides of the fuselage, which could affect the structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by April 14, 2014.

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

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

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

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–2014–0058; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0058; Directorate Identifier 2013–NM–116–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 based on those comments.

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

Discussion

On May 26, 1994, we issued AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994). AD 94–12–03 superseded AD 93–24–11, Amendment 39–8760 (58 FR 64875, December 10, 1993). AD 94–12–03 requires actions intended to address an unsafe condition on Airbus Model A320 series airplanes having serial numbers 0003 through 0092 inclusive. These serial numbers apply to Model A320–111, –211, and –231 series airplanes.

Since we issued AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994), The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2013–0122, dated June 5, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> During the fatigue test campaign of the A320 family type design, cracks have been found at the lower riveting of the four titanium angles which connect the belly fairing to the keel beam side panels between frames FR40 and FR42, on both sides of the fuselage.
>
> This condition, if not detected and corrected, could affect the structural integrity of the aeroplane.
>
> In 1992, DGAC France issued AD 92–201–030 (*http://ad.easa.europa.eu/blob/19922010tb_superseded.pdf/AD_F–1992–201–030_1*) (which corresponds to FAA AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994)) to require reinforcement of the belly fairing structure, which addressed part of the unsafe condition.
>
> For the reason described above, this [EASA] AD retains the requirements of DGAC France AD 92–201–030, which is superseded, and requires repetitive detailed inspections [for cracking] of the affected titanium angles and, depending on findings, repair or replacement of parts.

As an option to extend the repetitive inspection interval, after the first detailed inspection is accomplished and on condition of no crack findings, this proposed AD would allow operators to remove the four titanium angles, perform a rototest for cracking on the open holes and, provided no cracks are found, install new titanium angles, followed by post-modification detailed inspections of the new titanium angles.

For any titanium angle crack findings, this proposed AD would require removing any cracked angle, performing a rototest for cracking on the open holes and, provided no cracks are found, installing a new titanium angle, followed detailed inspections of the new titanium angles.

For any hole cracking found during any rototest, this proposed AD would require repair.

This proposed AD expands the applicability of AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994) to include all Airbus Model A318, Model A319, Model A320, and Model A321 series airplanes.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0058.

Relevant Service Information

Airbus has issued Service Bulletin A320–53–1014, Revision 02, dated September 1, 1994; and Service Bulletin A320–53–1259, dated November 6, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

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

Repair Approvals

In many FAA transport ADs, when the service information specifies to contact the manufacturer for further instructions if certain discrepancies are found, we typically include in the AD a requirement to accomplish the action using a method approved by either the FAA or the State of Design Authority (or its delegated agent).

We have recently been notified that certain laws in other countries do not allow such delegation of authority, but some countries do recognize design approval organizations. In addition, we have become aware that some U.S. operators have used repair instructions that were previously approved by a State of Design Authority or a Design Approval Holder (DAH) as a method of compliance with this provision in FAA ADs. Frequently, in these cases, the previously approved repair instructions come from the airplane structural repair manual or the DAH repair approval statements that were not specifically developed to address the unsafe condition corrected by the AD. Using repair instructions that were not specifically approved for a particular AD creates the potential for doing repairs that were not developed to address the unsafe condition identified by the MCAI AD, the FAA AD, or the applicable service information, which could result in the unsafe condition not being fully corrected.

To prevent the use of repairs that were not specifically developed to correct the unsafe condition, this proposed AD would require that the repair approval specifically refer to the FAA AD. This change is intended to clarify the method of compliance and to provide operators with better visibility of repairs that are specifically developed and approved to correct the unsafe condition. In addition, we use the phrase ''its delegated agent, or by the DAH with State of Design Authority design organization approval, as applicable'' in this proposed AD to refer to an DAH authorized to approve required repairs for this proposed AD.

Costs of Compliance

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

The actions that are required by AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994), and retained in this proposed AD take about 288 work-hours per product, at an average labor rate of $85 per work-hour. Required parts cost about $1,045 per product. Based on these figures, the estimated cost of the actions that were required by AD 94–12–03 is $25,525 per product.

We also estimate that it would take about 7 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $506,345, or $595 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions and optional action costs specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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 removing airworthiness directive (AD) 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994), and adding the following new AD:

Airbus: Docket No. FAA–2014–0058; Directorate Identifier 2013–NM–116–AD.

(a) Comments Due Date

We must receive comments by April 14, 2014.

(b) Affected ADs

This AD supersedes AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994).

(c) Applicability

This AD applies to the Airbus airplanes specified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, all manufacturer serial numbers.

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

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

(3) Airbus Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes.

(4) Airbus Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

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

(e) Reason

This AD was prompted by reports of cracks at the lower riveting of the four titanium angles that connect the belly fairing to the keel beam side panels on both sides of the fuselage. We are issuing this AD to detect and correct cracking of the titanium angles that connect the belly fairing to the keel beam side panels on both sides of the fuselage, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Retained Modification

This paragraph restates the requirements of paragraph (a) of AD 94–12–03, Amendment 39–8930 (59 FR 28763, June 3, 1994), with new service information. For Model A320–111, –211, and –231 series airplanes, manufacturer serial numbers 0003 through 0092 inclusive: Prior to the accumulation of 12,000 total landings on the airplane, or within 300 days after January 10, 1994 (the effective date of AD 93–24–11, Amendment 39–8760 (58 FR 64875, December 10, 1993)), whichever occurs later, modify the belly fairing structure, in accordance with the Accomplishment Instructions of an Airbus service bulletin specified in paragraph (g)(1), (g)(2), or (g)(3) of this AD. As of the effective date of this AD, use only the Airbus service bulletin specified in paragraph (g)(3) of this AD.

(1) Airbus Service Bulletin A320–53–1014, dated June 25, 1992.

(2) Airbus Service Bulletin A320–53–1014, Revision 1, dated May 26, 1993.

(3) Airbus Service Bulletin A320–53–1014, Revision 2, dated September 1, 1994.

(h) New Requirement of This AD: Repetitive Inspection

At the latest of the compliance times specified in paragraphs (h)(1), (h)(2), and (h)(3) of this AD: Do a detailed inspection for cracking of the four titanium angles between the belly fairing and the keel beam side panel, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1259, dated November 6, 2012.

(1) Before the accumulation of 30,000 total flight cycles or 60,000 total flight hours, whichever occurs first after first flight of the airplane.

(2) Within 30,000 flight cycles or 60,000 flight hours, whichever occurs first after modification of the airplane as required by paragraph (g) of this AD, or after installation of new titanium angles, provided that, prior to installation, a rototest for cracking on the open holes has been accomplished with no crack findings, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1259, dated November 6, 2012.

(3) Within 3,000 flight cycles or 6,000 flight hours, whichever occurs first after the effective date of this AD.

(i) New Requirement of This AD: Post-Inspection Actions for No Crack Findings

If, during any inspection required by paragraph (h) of this AD, there is no crack finding: Accomplish the actions specified in either paragraph (i)(1) or (i)(2) of this AD.

(1) Repeat the inspection required by paragraph (h) of this AD at intervals not to exceed 5,000 flight cycles or 10,000 flight hours, whichever occurs first.

(2) Before further flight after the inspection required by paragraph (h) of this AD, remove all inspected titanium angles, accomplish a rototest for cracking on the open holes and, provided no cracks are found, install new titanium angles, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1259, dated November 6, 2012.

(j) New Requirement of This AD: Post-Inspection Actions for Any Crack Findings

If, during any inspection required by paragraph (h) of this AD, there is any crack finding: Before further flight, remove the affected titanium angle(s), accomplish a rototest for cracking on the open holes, and, provided no cracks are found, install new titanium angles, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1259, dated November 6, 2012.

(k) New Requirement of This AD: Post-Installation Repetitive Inspections

For airplanes on which new titanium angles were installed as specified in paragraph (i)(2) or (j) of this AD: Within 30,000 flight cycles or 60,000 flight hours, whichever occurs first after the installation: Accomplish a detailed inspection for cracking of the four titanium angles between the belly fairing and the keel beam side panel, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1259, dated November 6, 2012. Repeat the inspection thereafter at intervals not to exceed 5,000 flight cycles or 10,000 flight hours, whichever occurs first.

(l) New Requirement of This AD: Post Inspection Actions for Any Crack Findings During Post-Installation Inspections

If, during any inspection as required by paragraph (k) of this AD, there is any crack finding: Before further flight, remove the affected titanium angles, accomplish a rototest for cracking on the open holes, and, provided no cracks are found, install new titanium angles, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1259, dated November 6, 2012.

(m) New Requirement of This AD: Corrective Action for Rototest Crack Finding

If, during any rototest as required by paragraph (i), (j), or (l) of this AD, any crack is found: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent, or by the Design Approval Holder (DAH) with EASA design organization approval, as applicable). For a repair method to be approved, the repair approval must specifically refer to this AD.

(n) New Provision of This AD: No Termination Action for Repetitive Inspections

Repair or replacement of parts as specified in this AD does not terminate the repetitive inspections required by this AD.

(o) Other FAA AD Provisions

The following provisions also apply to this AD:

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

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer, use these actions if they are FAA approved. Corrective actions are considered FAA-approved if they were approved by the State of Design Authority (or its delegated agent, or the Design Approval Holder with a State of Design Authority's design organization approval, as applicable). You are required to ensure the product is airworthy before it is returned to service.

(p) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency Airworthiness Directive 2013–0122, dated June 5, 2013, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0058.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61

93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on: February 18, 2014.

Ross Landes,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–04140 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0108; Directorate Identifier 2013–CE–052–AD]

RIN 2120–AA64

Airworthiness Directives; Mitsubishi Heavy Industries, Ltd. Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Mitsubishi Heavy Industries, Ltd. Models MU–2B–30, MU–2B–35, MU–2B–36, MU–2B–36A, and MU–2B–60 airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as stress corrosion cracking in the flanges of the airframe at stations 4610 and 5605. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 14, 2014.

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

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

For service information identified in this proposed AD, contact Mitsubishi Heavy Industries America, Inc., c/o Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248–3108, ext. 209; fax: (972) 248–3321; Internet: *http://mu-2aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0108; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Cook, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office (ACO), 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone: (817) 222–5475; fax: (817) 222–5960; email: *Kenneth.A.Cook@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0108; Directorate Identifier 2013–CE–052–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The Japan Civil Aviation Bureau (JCAB), which is the aviation authority for Japan, has issued AD No. TCD–8231–2013, dated August 6, 2013 (referred to after this as ''the MCAI''), to correct an unsafe condition for certain Mitsubishi Heavy Industries, Ltd. (MHI) Models MU–2B–30, MU–2B–35, and MU–2B–36 airplanes. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0108.

The JCAB has informed us that as part of the MHI continuing aging aircraft program, Models MU–2B–30, MU–2B–35, and MU–2B–36 airplanes, short body and long body, were subjected to detailed teardown inspections. During the inspections, structural cracks in the flanges of some long body airplane frames were found at frame station (STA) 4610 and STA 5605. It has been determined that the structural cracks resulted from stress corrosion.

Japan is the State of Design for Mitsubishi Heavy Industries, Ltd. (MHI) Models MU–2B–30, MU–2B–35, and MU–2B–36, which the MCAI AD applies to, and the United States is the State of Design for MHI Models MU–2B–36A and MU–2B–60 airplanes. Since the Models MU–2B–36A and MU–2B–60 airplanes are of similar type design, the same structural cracks could exist.

Relevant Service Information

Mitsubishi Heavy Industries, Ltd. has issued Service Bulletin No. 242, dated July 10, 2013, and Service Bulletin No. 104/53–003, dated July 22, 2013. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

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

Since the same unsafe condition exists for both the Japan and U.S. State of Design model airplanes, we are proposing one AD to address this issue for all affected airplanes.

This proposed AD would require inspecting the side and lower frame at STA 4610 and 5605 for cracks and corrosion and making all necessary repairs and replacements.

Costs of Compliance

We estimate that this proposed AD will affect 119 products of U.S. registry. We also estimate that it would take about 100 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $1,011,500, or $8,500 per product.

In addition, we estimate that any necessary follow-on actions would take up to 428 work-hours and require parts costing up to $14,400, for a cost up to $50,780 per product. We have no way of determining the number of products that may need such repair based on the results of the proposed inspection. The extent of damage will vary on each airplane.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Mitsubishi Heavy Industries, Ltd.: Docket No. FAA–2014–0108; Directorate Identifier 2013–CE–052–AD.

(a) Comments Due Date

We must receive comments by April 14, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Mitsubishi Heavy Industries, Ltd. Models MU–2B–30, MU–2B–35, and MU–2B–36 airplanes, serial numbers 502 through 651, 653 through 660, and 662 through 696, and Models MU–2B–36A and MU–2B–60 airplanes, serial numbers 661SA, 697SA through 799SA, and 1501SA through 1569SA, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as stress corrosion cracking in the flanges of the airframes at stations 4610 and 5605. We are issuing this AD to detect and correct structural cracks in the airframe flanges, which could reduce the structural integrity of the airplane.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (f)(3) of this AD.

(1) Within the next 1,000 hours time-in-service (TIS) after the effective date of this AD or within the next 3 years after the effective date of this AD, whichever occurs first, inspect the side and lower frames at frame station (STA) 4610 and STA 5605 for cracks and corrosion. Do the inspection following paragraphs 3.0 through 3.3 of Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 242, dated July 10, 2013, or Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 104/53–003, dated July 22, 2013, as applicable.

(2) If any crack is found during the inspection required in paragraph (f)(1) of this AD, before further flight, do the actions in paragraphs (f)(2)(i) or (f)(2)(ii) of this AD:

(i) Repair the frame following paragraphs 4.0 and 5.0 of Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 242, dated July 10, 2013, or Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 104/53–003, dated July 22, 2013, as applicable; or

(ii) Replace the frame following paragraphs 4.0, 6.0, and 7.0 of Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 242, dated July 10, 2013, or Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 104/53–003, dated July 22, 2013, as applicable.

(3) If any corrosion is found during the inspection required in paragraph (f)(1) of this AD, before further flight, repair the damage following the instructions in paragraph 3.2 of Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 242, dated July 10, 2013, or Mitsubishi Heavy Industries, Ltd. Service Bulletin No. 104/53–003, dated July 22, 2013, as applicable.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Kenneth A. Cook, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office (ACO), 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone: (817) 222–5475; fax: (817) 222–5960; email: *Kenneth.A.Cook@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of

information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Special Flight Permit

We are allowing special flight permits with the following limitations:

(1) Essential crew only;
(2) Minimum weight;
(3) Limit ''G'' loading to minimum; and
(4) Most direct flight to repair center.

(i) Related Information

Refer to MCAI Japan Civil Aviation Bureau (JCAB) AD No. TCD–8231–2013, dated August 6, 2013, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0108. For service information related to this AD, contact Mitsubishi Heavy Industries America, Inc. c/o Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248–3108, ext. 209; fax: (972) 248–3321; Internet: *http://mu-2aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on February 20, 2014.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–04146 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1101

[CPSC Docket No. CPSC–2014–0005]

Information Disclosure Under Section 6(b) of the Consumer Product Safety Act

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (Commission, CPSC, or we) is issuing this notice of proposed rulemaking (NPR) to update the regulation that interprets section 6(b) of the Consumer Product Safety Act (CPSA). In 1983, the Commission issued a regulation interpreting the provisions of section 6(b) of the CPSA, and we are proposing to modernize that regulation to account for the significant improvements in information technology that have occurred since the regulation's adoption. We are also proposing to streamline the regulation to be as closely aligned with section 6(b) as possible, while maintaining our compliance with the statutory requirements and the protections of section 6(b)(5) for information filed in accordance with the requirements of section 15(b) of the CPSA. This NPR seeks comments on the proposed changes to the regulation.

DATES: Written comments must be received by April 28, 2014.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2014–0005, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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

The Commission is no longer accepting comments submitted by electronic mail (email), except through: *http://www.regulations.gov.*

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rule. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing, with the sensitive portions clearly identified.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Todd A. Stevenson, Secretariat, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone (301) 504–6836; *tstevenson@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 6(b) of the CPSA governs information disclosure by the Commission to the public. When disclosing information, the Commission, to the extent practicable, shall notify each manufacturer or private labeler of information to be disclosed that ''pertains'' to a consumer product, if the information ''will permit the public to ascertain readily the identity of [the] manufacturer or private labeler'' of the product. 15 U.S.C. 2055(b). Section 6(b)(1) also requires the Commission to ''take reasonable steps to assure'' that the information to be disclosed ''is accurate, and that [its] disclosure is fair in the circumstances and reasonably related to effectuating the purposes of [the CPSA].'' *Id.* In 1980, the U.S. Supreme Court ruled that disclosures under the Freedom of Information Act (FOIA) are covered by the section 6(b)(1) restrictions. *Consumer Product Safety Commission* v. *GTE Sylvania, Inc.,* 447 U.S. 102 (1980).

On December 29, 1983, we published a final rule interpreting section 6(b) of the CPSA. 48 FR 57430. The rule, 16 CFR part 1101, describes our procedures for providing manufacturers and private labelers with advance notice and ''a reasonable opportunity to submit comments'' to the Commission on proposed disclosures of product-specific information. The rule also explains the ''reasonable steps'' we will take pursuant to section 6(b) to assure, prior to public disclosure of product-specific information, that (1) the information is accurate; (2) disclosure of the information is fair in the circumstances; and (3) disclosure of the information is reasonably related to effectuating the purposes of the statutes the Commission administers.

The Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110–314, 122 Stat. 3016, enacted on August 14, 2008, amended section 6 of the CPSA. The amendments shortened the time periods from 30 to 15 days for manufacturers and private labelers to receive advance notice and have an opportunity to comment on any disclosure to the public of product-specific information. In addition, the amendments eliminated the requirement that the Commission publish a **Federal Register** notice when the Commission makes a finding that the public health and safety necessitates

public disclosure within a lesser period of notice than required by section 6(b)(1). The amendments also broadened the statutory exceptions to section 6(b). For example, the amendments excluded from section 6(b) the public disclosure of information with respect to a consumer product which the Commission has reasonable cause to believe is in violation of any consumer product safety rule or provision under the CPSA or similar rule or provision of any other Act enforced by the Commission. On November 28, 2008, we published a final rule to reflect these statutory amendments. 73 FR 72335.

On May 3, 2013, the Commission voted (2–1) to approve, with changes, the Fiscal Year 2013 Midyear Review and Operating Plan Adjustments (FY 2013 Midyear Adjustments), which directed staff to present for Commission consideration, an NPR updating the rule in accordance with the following guiding principles:

1. Modernize the rule to account for the significant advancements in information technology that have taken place since its initial adoption in 1983;

2. streamline the rule to be as closely aligned with 15 U.S.C. 2055(b) as possible, with the objectives of (a) eliminating unnecessary administrative burdens to the agency, (b) removing extra-statutory requirements, (c) eliminating redundancies in providing notice, (d) minimizing Freedom of Information Act (FOIA) backlogs, and (e) maximizing transparency and openness in our disclosure of information;

3. maintain CPSC's compliance with the statutory requirements of 15 U.S.C. 2055(b) (*i.e.,* requirements related to notice, opportunity to submit comments, and taking reasonable steps to assure accuracy, fairness in the circumstances, and reasonable relation to effectuating the purposes of the CPSA outlined in 15 U.S.C. 2051(b)); and

4. maintain the protections of 15 U.S.C. 2055(b)(5) for information filed in accordance with the requirements of 15 U.S.C. 2064(b) (*e.g.,* Section 15(b) reports).

See http://www.cpsc.gov//Global/Newsroom/FOIA/Records-of-Commission-Action-and-Meeting-Minutes/RCAFY13MidyearReviewandOperatingPlanAdjustments%20050313.pdf. The Commission is proposing this amendment to update the rule in accordance with the principles specified in the FY 2013 Midyear Adjustments. This proposed amendment also contains technical revisions, including typographical and citation corrections, and changes to conform the rule to the statute.[1]

II. Description of the Proposed Rule

The proposal would amend Title 16 of the Code of Federal Regulations: Part 1101, titled ''Information Disclosure Under Section 6(b) of the Consumer Product Safety Act.'' We describe each proposed amendment in detail immediately below.

1. Proposed Changes to the Table of Contents

In § 1101.12, remove: ''Commission must disclose information to the public'' and in its place, add: ''Definition of ''public''.''

2. Proposed Changes to § 1101.1 (General background.)

Section 1101.1(b) sets forth the statutory requirements on which the regulation is based. Currently, the last sentence of § 1101.1(b)(1) states: ''Additional limitations on the disclosure of information reported to the Commission under section 15(b) of the CPSA are established in section 6(b)(5).'' Pursuant to section 6(b)(5), the Commission shall not disclose to the public information submitted to the Commission under section 15(b) of the CPSA. The section 6(b)(5) limitations, however, do not apply to the public disclosure of:

1. Information with respect to a consumer product which is the subject of an action brought under section 12;

2. information with respect to a consumer product which the Commission has reasonable cause to believe is in violation of any consumer product safety rule or provision under the CPSA or similar rule or provision of any other Act enforced by the Commission; or

3. information in the course of or concerning a judicial proceeding.

Accordingly, we propose clarifying the last sentence of § 1101.1(b)(1) to state: ''Section 6(b)(5) creates additional limitations, as well as exceptions to these limitations, on the disclosure of information reported to the Commission under section 15(b) of the CPSA.''

In addition, we propose the following technical changes to § 1101.1:

A. In § 1101.1(b)(1), insert: ''calendar'' between ''15'' and ''days''.

B. In § 1101.1(b)(1), remove: ''Exceptions to these requirements are established in section 6(b)(4)'' and in its place, add: ''Section 6(b)(4) establishes exceptions to these requirements''.

C. In the last sentence of § 1101.1(c), remove: ''April 27, 1983'' and in its place, add: ''January 16, 2003.)''.

3. Proposed Changes to § 1101.2 (Scope.)

We propose the following technical changes to § 1101.2:

A. Remove the statutory citation: ''2085'' and in its place, add: ''2089''.

B. Remove the statutory citation: ''1476'' and in its place, add: ''1477''.

C. Remove the statutory citation: ''1276'' and in its place, add: ''1278a''.

D. Remove: ''These provisions are now applicable to the Virginia Graeme Baker Pool and Spa Safety Act, 15 U.S.C. 8003(a); and the Children's Gasoline Burn Prevention Act § 2(a), Public Law 110–278, 122 Stat. 2602 (July 17, 2008)'' and in its place, add: ''These provisions also apply to the Child Safety Protection Act 101 and 102, Public Law 103–267, 108 Stat. 722 (June 16, 1994) (CSPA); the Virginia Graeme Baker Pool and Spa Safety Act, 15 U.S.C. 8003(a) (VGBA); and the Children's Gasoline Burn Prevention Act 2(a), Public Law 110–278, 122 Stat. 2602 (July 17, 2008) (CGBPA)''.

4. Proposed Changes to § 1101.11 (General Application of Provisions of Section 6(b)(1).)

Section 1101.11(a) sets forth information subject to section 6(b)(1) of the CPSA. Section 6(b)(1) requires the Commission to provide notice and an opportunity to comment to each manufacturer or private labeler if the manner in which a consumer product is designated or described in the information proposed for disclosure ''will permit the public to ascertain readily the *identity of such manufacturer or private labeler''* (emphasis added). Currently, § 1101.11(a)(1) deviates from the statutory language, stating: ''The information must pertain to a specific product which is either designated or described in a manner which permits its identity to be ascertained readily by the public.'' We propose revising this provision to conform to the language contained in section 6(b)(1). Specifically, section 6(b)(1) requires notice and an opportunity to comment only if the identity of the manufacturer or private labeler can be ascertained readily by the public. Section 6(b)(1) does not require that the identity of the *product* be ascertained readily by the public. Therefore, to be as closely aligned with the statutory language as possible, we propose removing from § 1101.11(a)(1) the phrase: ''which is either designated or described in a manner which permits its identity to be

[1] The Commission voted 2–1 to approve the Proposed Rule as amended.

ascertained readily by the public''. Proposed § 1101.11(a) would state: ''(1) The information must pertain to a specific product.''

Currently, § 1101.11(a)(2) states: ''The information must be obtained, generated or received by the Commission as an entity or by individual members, employees, agents, contractors or representatives of the Commission acting in their official capacities.'' This statement differs from the language in section 6(b). Section 6(b) applies to the ''public disclosure of any information obtained under this Act, or to be disclosed to the public in connection therewith.'' 15 U.S.C. 2055(b). We propose revising § 1101.11(a)(2) to state: ''The information must be obtained under the acts the Commission administers, or be disclosed to the public in connection therewith.'' Although the Commission would be conforming our regulation to relevant statutory language with this change, there is no expectation that it would reduce the scope of information subject to 6(b) requirements.

Section 1101.11(b) sets forth information not subject to the requirements of section 6(b)(1). Currently, § 1101.11(b)(1) states: ''Information described in the exclusions contained in section 6(b)(4) of the CPSA (see subpart E of this rule).'' As discussed above, in § 1101.1, section 6(b)(5)'s limitations on the disclosure of information reported to the Commission under section 15(b) of the CPSA do not apply to the public disclosure of:

1. Information with respect to a consumer product which is the subject of an action brought under section 12;

2. information with respect to a consumer product which the Commission has reasonable cause to believe is in violation of any consumer product safety rule or provision under the CPSA or similar rule or provision of any other act enforced by the Commission; or

3. information in the course of or concerning a judicial proceeding.

We propose revising § 1101.11(b)(1) to clarify that the requirements of section 6(b)(1) do not apply to these exceptions. Proposed § 1101.11(b)(1) would state: ''Information described in the exclusions contained in section 6(b)(4) or (b)(5) of the CPSA (see subpart E and G of this rule).''

In addition to specifying these exceptions in the rule, we are proposing to include three other categories of information not subject to the requirements of section 6(b). Not only will these additions conform to new statutory requirements established by the CPSIA, but the additions also will maximize transparency and openness in our disclosure of information. Therefore, we propose adding the following three categories to the list of information not subject to the notice and comment requirements of section 6(b)(1):

1. A report of harm posted on the publicly available consumer product safety information database.

2. information that is publicly available.

3. information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1), except as specified in § 1101.31(d).

Section 6A(f)(1) of the CPSA specifically excludes reports of harm posted on the publicly available consumer product safety information database from the provisions of section 6(b). To reflect this statutory exclusion, we propose revising § 1101.11(b) to include the following category: ''(6) A report of harm posted on the publicly available consumer product safety information database pursuant to section 6A of the CPSA, 15 U.S.C. 2055a.''

Section 6(b) is intended to provide firms with a review process before the Commission discloses to the public information obtained by the Commission under the CPSA. Information already in the public domain has not been obtained by the Commission under the CPSA, nor would the section 6(b) process serve any purpose with respect to information already disclosed other than by the Commission. Neither the statute nor the legislative history suggests that information that is readily available to the public is, or should be, subject to section 6(b)(1). To increase transparency, we propose revising § 1101.11(b) to include the following category: ''(7) Information that is publicly available or that has been disseminated in a manner intended to reach the public in general, such as news reports; articles in academic and scientific journals; press releases distributed through news or wire services; or information that is available on the Internet.''

This revision in the proposed rule, however, does not change the Commission's obligations under both existing CPSC policy and federal law to assure that information disclosed by the CPSC to the public is accurate (CPSC Order 1450.2, Jan. 16 2003) and presented in an accurate, clear, complete, and unbiased manner. (Information Quality Act, Treasury and General Government Appropriations Act for Fiscal Year 2001 sec. 515, Pub. L. 106–554, 144 Stat. 2763 (2001) and OMB Guidelines 67 FR 8452 (Feb. 22, 2002)). The Commission also notes that other federal health and safety agencies that do not operate under section 6(b)'s legal restrictions still generally coordinate the release of information identifying specific manufacturers with those manufacturers. These agencies do this in the name of assuring accuracy and fairness—concepts that the Commission endorses even absent the restrictions contained in section 6(b).

We also propose adding to the list of information that is not subject to section 6(b)(1) information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1). Section 6(b) does not require a new notice and comment process when the agency re-discloses information as to which appropriate notice already has been conveyed and applicable procedures followed.

Although renotification is not statutorily required, firms currently may request renotification, or the opportunity to comment on subsequent disclosures of identical information. *See* 16 CFR 1101.21(b)(7), 1101.31(d). The purpose of renotification was to provide firms with another occasion to submit substantive comments on information that the Commission previously released in accordance with the requirements of section 6(b).

Our review of the 6(b) process and firms' comments, however, reveals that few firms request renotification or provide substantive claims concerning accuracy, fairness, or reasonable relation to effectuating the purposes of the statutes the Commission administers for the staff to evaluate prior to releasing the information. For example, in calendar year 2012, approximately 25 percent of firms that received an initial notice requested renotification. During the same period, the Commission renotified firms on 40 separate occasions. In the majority of these cases, the firms never responded, responded but did not provide any comments on the information, or simply repeated the same claims that they submitted in response to the initial notice without providing any additional information for the staff to evaluate. Renotification thus generally has not resulted in new substantive input to staff [nor has the renotification process yielded re-disclosures that are handled differently from initial disclosures]. In short, renotification in practice duplicates the initial notification process and result. As a result, and in light of the absence of any statutory requirement for

renotification, we propose removing this provision from the regulation.

Of course, if a firm subsequently discovers new information that is relevant to information the Commission previously released, such as a reported incident, the firm may supplement its initial comments to the Commission. In addition, the requirements of section 6(b)(1) will apply if the Commission has reason to question the accuracy of the information proposed for a subsequent release, as specified in the proposed revision to § 1101.31(d). Therefore, we propose revising § 1101.11(b) to include the following category: ''(8) Information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1), except as specified in § 1101.31(d).''

In addition, we propose the following technical and conforming changes to § 1101.11:

A. In § 1101.11(a)(3), remove: ''The Commission or its members, employees, agents or representatives must propose to disclose the information to the public (see § 1101.12)'' and in its place, add: ''The Commission, any member of the Commission, or any employee, agent, or representative, including contractor, of the Commission in an official capacity must propose to disclose the information to the public (see § 1101.12)''.

B. In § 1101.11(b)(2), remove the statutory citation: ''2068(b)'' and in its place, add: ''2067(b)''.

C. In § 1101.11(b)(2), remove the regulatory citation: ''16 CFR part 1017'' and in its place, add: ''16 CFR part 1019''.

5. Proposed Changes to § 1101.12 (Commission Must Disclose Information to the Public)

We propose the following technical and conforming changes to § 1101.12:

A. Remove the heading: ''Commission must disclose information to the public'' and in its place, add: ''Definition of ''public''.''

B. In § 1101.12(a), remove: ''Members, employees, agents, representatives and contractors of the Commission, in their official capacity'' and in its place, add: ''Any member of the Commission or any employee, agent, or representative, including contractor, of the Commission in an official capacity''.

C. In § 1101.12(d), remove: ''whom'' and in its place, add: ''which''.

D. In § 1101.12(f), remove: ''Federal'' and in its place, add: ''federal'' wherever ''Federal'' appears.

E. In § 1101.12(f), remove: ''whom'' and in its place, add: ''which''.

6. Proposed Changes to § 1101.13 (Public Ability to Ascertain Readily Identity of Manufacturer or Private Labeler)

Currently, § 1101.13 states: ''The advance notice and analysis provisions of section 6(b)(1) apply only when a reasonable person receiving the information in the form in which it is to be disclosed and lacking specialized expertise can readily ascertain from the information itself the identity of the manufacturer or private labeler of a particular product. The Commission will provide the advance notice and opportunity to comment if there is a question whether the public could readily ascertain the identity of a manufacturer or private labeler.''

We propose deleting from § 1101.13 the following sentence: ''The Commission will provide the advance notice and opportunity to comment if there is a question whether the public could readily ascertain the identity of a manufacturer or private labeler.'' The Commission adopted a ''reasonable person'' standard in § 1101.13 for determining whether the advance notice and analysis provisions of section 6(b)(1) would apply to information proposed for disclosure. Under this standard, if a reasonable person who lacks specialized expertise can readily ascertain the identity of the firm from the information proposed to be disclosed, the information will be forwarded to the firm for section 6(b) comment. The Commission included the sentence proposed for deletion when we adopted the final rule in 1983 in response to comments that we received. 48 FR 57409. Because we believe this sentence is vague and inconsistent with the reasonable person standard that the Commission adopted, we propose deleting the sentence from § 1101.13. The Commission believes that in practice the reasonable person standard as implemented in the context of interpreting proposed section 1101.13 errs in favor of providing notice to manufacturers and private labelers.

In addition, we propose the following technical change to § 1101.13:

A. Remove: ''it'' and in its place, add: ''the information''.

7. Proposed Changes to § 1101.21 (Form of Notice and Opportunity to Comment.)

Section 6(b) requires the Commission to ''notify'' manufacturers or private labelers of consumer products before public disclosure of product-related information covered by the statute. Section 6(b) does not prescribe the medium to be used for providing the notice. Similarly, § 1101.21 prescribes oral or written notice, but does not specify the medium to be used for written notice.

There have been significant advancements in information technology and communication since we adopted the rule in 1983. As a result, use of electronic means to provide notice is widely accepted by other federal departments and agencies and courts, among others.

Despite these advancements, the Commission continues to provide 6(b) notice to firms via U.S. mail, a more time-consuming practice that incurs unnecessary costs, particularly from printing and mailing the relevant documents. In addition, staff resources are dedicated to preparing these paper mailings.

To increase efficiency and limit unnecessary expenditures of staff resources, we propose revising the rule to permit electronic 6(b) notices, to direct the Commission to transmit requisite notices through an electronic medium whenever possible, and to encourage electronic communication with the Commission. To this end, the Commission proposes the following changes to § 1101.21:

A. Insert ''(1)'' before the sentence, ''The Commission will generally provide manufacturers or private labelers written notice and opportunity to comment on information subject to section 6(b)(1).''

B. Insert the following statements after the last sentence in § 1101.21(a): ''(2) Any notice required to be given under the provisions of this Part 1101 may be transmitted using electronic means of communication. Whenever possible, the Commission will transmit such notice electronically.''

C. In § 1101.21(b)(8), insert: ''applicable contact information for electronic communication,'' between ''address,'' and ''and telephone number''.

Section 1101.21(b) specifies the information that will appear in a section 6(b) notice. Currently, § 1101.21(b)(5) states: ''A statement that a request that comments be withheld from disclosure will be honored.'' As described below, in § 1101.31, we propose requiring a rationale, that seeks to achieve a reasonable balance between the public interest in transparency and the rights of identified firms to be assured that disclosure is fair under the circumstances. A firm's rationale may take various forms, such as a specific statutory or regulatory basis or provision or a description of why disclosure of the comment would be unfair in the totality of the circumstances.

Adopting these revisions, proposed § 1101.21(b)(5) would state: ''A statement that if the manufacturer or private labeler objects to disclosure of its comments or a portion thereof, the manufacturer or private labeler must notify the Commission of such objection at the time the manufacturer or private labeler submits its comments, provide a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed, and explain why disclosure of the comments is not fair in the circumstances or is not reasonably related to effectuating the purposes of the CPSA.''

Currently, § 1101.21(b)(7) states: ''A statement that no further request for comment will be sought by the Commission if it intends to disclose the identical information in the same format, unless the firm specifically requests the opportunity to comment on subsequent information disclosures.'' In § 1101.31, the phrase, ''identical information in the same format,'' requires the Commission to provide 6(b) notice for subsequent disclosures of information that may differ only slightly, without any impact on accuracy, from the information the Commission initially released in accordance with section 6(b). The statute by its terms does not require 6(b) notice for changes in the appearance of the information or for minor editorial changes. Therefore, we propose revising the phrase to state: ''information that is substantially the same''. In addition, as discussed above, in § 1101.11, we propose removing renotification from the rule. The renotification process, which is not required under the statute, has not resulted in new substantive input to staff. For these reasons, the Commission proposes revising § 1101.21(b)(7) to state: ''A statement that no further request for comment will be sought by the Commission if the Commission intends to disclose information that is substantially the same as the information that the Commission previously disclosed.''

In addition, we propose the following technical and conforming changes to § 1101.21:

A. In § 1101.21(a)(1), remove: ''the Commission may determine that it is necessary to provide the notice and opportunity to comment orally, either in person or by telephone'' and in its place, add: ''the Commission may determine that notice and opportunity to comment orally is necessary''.

B. In § 1101.21(b), remove: ''The Commission will provide the manufacturer or private labeler with'' and in its place, add: ''The Commission shall, to the extent practicable, provide the manufacturer or private labeler with''.

8. Proposed Changes to § 1101.22 (Timing: Request for Time Extensions.)

Section 1101.22(a) explains the time for comment. Currently, § 1101.22(a)(1) states: ''Generally firms will receive ten (10) calendar days from the date of the letter in which the Commission transmits the notice to furnish comments to the Commission. Firms that receive requests for comments by mail will receive an additional three (3) days to comment to account for time in the mail.'' As discussed above, in § 1101.21, to increase efficiency and limit unnecessary expenditures of staff resources, we propose revising the rule to encourage electronic communication with the Commission whenever possible. Proposed § 1101.22(a)(1) would state: ''In the interest of promoting timely notification, the Commission, whenever possible, will transmit electronically to the manufacturer or private labeler the notice to furnish comments to the Commission. Generally firms will receive ten (10) calendar days from the date of such notice. Firms that receive notice by mail will receive an additional three (3) calendar days to comment to account for time in the mail.''

Currently, the first sentence of § 1101.22(a)(2) reads: ''Upon his or her own initiative or upon request, the Freedom of Information Officer may provide a different amount of time for comment, particularly for firms that receive voluminous or complex material.'' We propose deleting from this sentence the phrase: ''Upon his or her own initiative or''. As a matter of practice since the rule was enacted, the Freedom of Information Officer generally has not determined on his own initiative whether a firm would require additional time to comment on information proposed for disclosure. If a firm requires such additional time, the firm may submit an extension request to the Freedom of Information Officer for consideration. To account for actual practice, we propose revising the first sentence of § 1101.22(a)(2) to read: ''Upon request, the Freedom of Information Officer may provide a different amount of time for comment, particularly for firms that receive voluminous or complex material.''

Section 1101.11(b) explains the Commission's process if a firm does not respond to the Commission's 6(b) notice. Currently, § 1101.22(b)(2) reads: ''Unless the Commission publishes a finding that the public health and safety requires a lesser period of notice (see § 1101.23), the Commission will not disclose the information in fewer than 15 days after providing a manufacturer or private labeler notice and opportunity to comment.'' As indicated in § 1101.23, in addition to publishing a finding that the public health and safety requires a lesser period of notice, the Commission may disclose information to the public in fewer than 15 days, if the firm agrees to a lesser period of notice, or does not object to the proposed disclosure. We propose revising § 1101.22(b)(2) to incorporate this provision. Proposed § 1101.22(b)(2) would state: ''The Commission will not disclose the information in fewer than 15 calendar days after providing a manufacturer or private labeler with notice and an opportunity to comment, unless (i) the firm agrees to a lesser period or does not object to disclosure, or (ii) the Commission publishes a finding that the public health and safety requires a lesser period of notice (see § 1101.23).''

In addition, we propose the following technical changes to § 1101.22:

A. In § 1101.22(a)(2), remove: ''§ 1101.24'' and in its place, add: ''§ 1101.23''.

B. In § 1101.22(b)(1), remove ''if it'' and insert a comma between ''submitted'' and ''the Commission.''

9. Proposed Changes to § 1101.23 (Providing Less Than 15 Days Notice Before Disclosing Information.)

As discussed above, in § 1101.21, the Commission, whenever possible, intends to communicate electronically with firms. Therefore, the Commission proposes inserting the following statement after the first sentence in § 1101.23(c): ''If written notice is provided, the Commission, whenever possible, will transmit such notice electronically.''

In addition, we propose the following technical and conforming changes to § 1101.23:

A. In § 1101.23, insert: ''calendar'' between ''15'' and ''days'' wherever ''15'' and ''days'' appear.

B. In § 1101.23(a), remove: ''it'' and in its place, add: ''the firm'' wherever ''it'' appears.

C. In the last sentence of § 1101.23(c), remove: ''Where applicable, before releasing information'' and in its place, add: ''Before releasing information''.

10. Proposed Changes to § 1101.24 (Scope of Comments Commission Seeks.)

Currently, § 1101.24(c) states: ''*Requests for nondisclosure of comments.* If a firm objects to disclosure of its comments or a portion thereof, it

must notify the Commission at the time it submits its comments. If the firm objects to the disclosure of a portion of its comments, it must identify those portions which should be withheld.'' As described more specifically below, in § 1101.31, we propose revising § 1101.24(c) to require a rationale to support withholding a firm's comments and an explanation of why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances. A statement requesting that comments be withheld without the firm providing a rationale will not be sufficient to withhold comments. Therefore, we propose revising § 1101.24(c) to state: ''If a firm objects to disclosure of its comments or a portion thereof, the firm must notify the Commission of such objection at the time the firm submits its comments, provide a rationale, such as a statutory or regulatory basis or provision, for why the comments should not be disclosed, and explain why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances. If the firm objects to the disclosure of a portion of its comments, the firm must specifically identify those portions that should be withheld. Conclusory statements that comments must be withheld with no supporting basis are not sufficient to justify a request for nondisclosure.''

In addition, we propose the following technical changes to § 1101.24(b):

A. In the first sentence, remove: ''which pertains to trade secret or other confidential material'' and in its place, add: ''which refers to trade secret or other confidential material and information subject to 5 U.S.C. 552(b)(4)''.

B. In the second sentence, remove: ''believes to be confidential or trade secret material and must state with specificity the grounds on which the firm bases it claims'' and in its place, add: ''believes to be confidential or trade secret material or subject to 5 U.S.C. 552(b)(4) and must state with specificity the grounds on which the firm bases its claims''.

11. Proposed Changes to § 1101.25 (Notice of Intent To Disclose.)

As discussed above, with respect to § 1101.21, the Commission is revising the rule in part to reflect the significant improvements in information technology since 1983. Therefore, we propose adding the following sentence to the end of § 1101.25(c): ''If written notice is provided, the Commission, whenever possible, will transmit such notice electronically.''

In addition, we propose the following technical changes to § 1101.25:

A. In § 1101.25, remove ''5 days'' and in its place, add: ''five (5) calendar days'' wherever ''5 days'' appears.

B. In the first sentence of § 1101.25(a), remove: ''that it intends'' and in its place, add: ''that the Commission intends''.

C. In the second sentence of § 1101.25(a), remove the comma between ''decision'' and ''copies'' and in its place, add: ''and''.

D. In the first sentence of § 1101.25(b), remove: ''its'' and in its place, add: ''the Commission's''.

E. In § 1101.25(b), remove the sentence: ''For example, the Commission may determine it is necessary to warn the public quickly because individuals may be in danger from a product hazard or a potential hazard, or to correct product safety information released by third persons, which mischaracterized statements made by the Commission about the product or which attributes to the Commission statements about the product which the Commission did not make'' and in its place, add: ''For example, the Commission may determine that the public must be warned more quickly than five (5) calendar days because of danger from a product hazard or a potential hazard, or to correct product safety information released by third persons, which mischaracterizes statements made by the Commission about the product or which inaccurately attributes to the Commission statements about the product''.

F. In the first sentence of § 1101.25(c), remove ''which'' and in its place, add: ''that''.

12. Proposed Changes to § 1101.31 (General Requirements.)

Currently, § 1101.31(b), which addresses the inclusion of a firm's comments, reads: ''In disclosing any information under this section, the Commission will include any comments or other information submitted by the manufacturer or private labeler unless the manufacturer or private labeler at the time it submits its section 6(b) comments specifically requests the Commission not to include the comments or to include only a designated portion of the comments and disclosure of the comments on such a designated portion is not necessary to assure that the disclosure of the information which is the subject of the comments is fair in the circumstances.'' We propose revising this sentence.

As an initial matter, the Commission must include with the disclosure, a firm's comments if the manufacturer or private labeler requests inclusion, and inclusion is permitted by and subject to the requirements of section 6(b)(1). 15 U.S.C. 2055(b)(1). In instances where the firm does not request disclosure, section 6(b)(1) grants the Commission discretion in releasing a firm's comments, stating that ''the Commission *may* . . . include with the disclosure any comments or other information or a summary thereof . . . to the extent permitted by and subject to the requirements of this section'' (emphasis added). *Id.*

When the Commission adopted the final rule in 1983 interpreting section 6(b)(1), we stated that we ''intend[] to follow the general policy of disclosing comments unless the manufacturer specifically requests they be withheld.'' 48 FR 57422. We recognized that a blanket policy always allowing a firm's comments to be withheld, even though the comments contained no confidential commercial or trade secret information, would not be a desirable outcome. 48 FR 57423. The Commission was concerned that such a policy ''would unnecessarily block the release of information, even though the Commission has taken the requisite reasonable steps to assure that the information is accurate and disclosure would be reasonably related to effectuating one or more purposes of the statutes the Commission administers.'' *Id.* We stated our belief that section 6(b) ''should not be construed to permit a firm to frustrate the disclosure of information simply by making a blanket claim of confidentiality for the information contained in its comments.'' *Id.* For firms that made blanket claims, the Commission stated in the preamble that we would notify the firm that disclosure of the firm's comments is necessary to assure that disclosure of the information was fair in the circumstances. In these instances, we would: (1) Ask a firm to summarize the firm's comments, or provide an edited version for public disclosure; (2) ask a firm to consent to the disclosure of information without the firm's comments; or (3) disclose the information ''with an explanatory statement that the manufacturer furnished data necessary to place the information in context but did not consent to its disclosure.'' *Id.*

Our review of how firms typically submit comments under section 6(b) and staff's subsequent processing of such comments, however, indicates that most comments are withheld. Most firms request that their comments be

maintained in confidence, even where the firms do not provide any specific comments on the disclosure, or do not object at all to disclosure of the information. For example, even when a firm's only comment is that the firm does not object to disclosure, the firm may request that this comment—that it has ''no objection to disclosure''—be withheld in confidence. Staff has withheld comments in this circumstance even though the comments state only that the firm has no objection to disclosure of the information. In effect, staff adopted a blanket policy of withholding where such a policy was never intended.

To obtain more substantive and useful information from firms who object to disclosure of comments, we are proposing to revise the regulation to require firms to provide a rationale for why comments should not be disclosed and an explanation of why disclosure of the comments is not necessary to assure that the disclosure of the information is fair in the circumstances. Conclusory assertions that comments be withheld without a rationale will not be sufficient to withhold comments. In addition, a firm's comment that it has no objection to disclosure, without any additional comments, will not be sufficient to justify withholding. Proposed § 1101.31(b) would state: ''In disclosing any information under this section, the Commission may, and upon the request of the manufacturer or private labeler shall, include any comments or other information or a summary thereof submitted by the manufacturer or private labeler to the extent permitted by and subject to the requirements of section 6(b). If the manufacturer or private labeler, at the time it submits its section 6(b) comments, specifically requests that the Commission not include the comments, or include only a designated portion of the comments, the manufacturer or private labeler must provide for evaluation by the Commission, a rationale, such as an applicable statutory or regulatory basis or provision, supporting such withholding and an explanation of why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances.''

Currently, § 1101.31(d), which pertains to information the Commission previously disclosed, reads: ''If the Commission has previously disclosed, in accordance with section 6(b)(1), the identical information it intends to disclose again in the same format, it will not customarily take any additional steps to assure accuracy unless the Commission has some reason to question its accuracy or unless the firm, in its comments responding to the Commission's initial section 6(b) notice, specifically requests the opportunity to comment on subsequent disclosures, or unless the Commission determines that sufficient time has passed to warrant seeking section 6(b) comment again. Before disclosing the information the Commission will again review the information to see if accuracy is called into question and will further look to whether disclosure is fair in the circumstances and reasonably related to effectuating the purposes of the Acts the Commission administers.''

We propose two revisions to this provision. First, we propose removing: ''If the Commission has previously disclosed, in accordance with section 6(b)(1), the identical information it intends to disclose again in the same format, it will not customarily take any additional steps to assure accuracy unless the Commission has some reason to question its accuracy'' and in its place, adding: ''If the Commission intends to disclose information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1), the Commission is not obligated to take any additional steps to assure accuracy unless the Commission has reason to question the accuracy of the information''. In its current form, the phrase, ''identical information it intends to disclose again in the same format,'' requires the Commission to provide 6(b) notice for subsequent disclosures of information that may differ only slightly, without any impact on accuracy, from the information the Commission initially released in accordance with section 6(b). When we adopted the final rule in 1983, the Commission specifically included ''same format'' in response to a comment that requested this addition. 48 FR 57414. The Commission agreed with the request, stating: ''the format of the disclosure (other than summaries of information previously released) or the intended audience may be of significant interest to the firm and may warrant comment.'' *Id.* Under a strict reading of the current provision, however, changes in the appearance of the information, such as the use of different fonts or layouts, and minor editorial changes, such as the insertion of a comma to the text, without any impact on the accuracy of the information, would require the Commission to provide subsequent 6(b) notice. We do not believe the statute requires subsequent 6(b) notice in these circumstances. In addition, we propose deleting the word, ''some,'' from the phrase, ''some reason.'' ''Reason'' provides the staff with a more definitive standard for when staff will take additional steps to assure accuracy.

Second, we propose deleting from § 1101.31(d) the following: ''or unless the firm, in its comments responding to the Commission's initial section 6(b) notice, specifically requests the opportunity to comment on subsequent disclosures, or unless the Commission determines that sufficient time has passed to warrant seeking section 6(b) comment again. Before disclosing the information the Commission will again review the information to see if accuracy is called into question and will further look to whether disclosure is fair in the circumstances and reasonably related to effectuating the purposes of the Acts the Commission administers.''

Regarding the first sentence on renotification, as discussed above, in § 1101.11, the majority of firms that receive renotification fail to respond, respond but do not provide any comments on the information, or simply repeat the same claims that they submitted in response to the initial notice, without providing any additional information for the staff to evaluate. The Commission proposes deleting renotification from § 1101.31(d). Regarding the second sentence, the statute does not require the Commission to conduct another 6(b) review for information that the Commission already has released to the public. For these reasons, we propose deleting these sentences from the regulation.

Incorporating the changes discussed above, proposed § 1101.31(d) would state: ''*Information previously disclosed.* If the Commission intends to disclose information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1), the Commission is not obligated to take any additional steps to assure accuracy unless the Commission has reason to question the accuracy of the information.''

We also propose the following technical and conforming changes to § 1101.31:

A. In § 1101.31(a), remove: ''The Commission will attempt to make its decision on disclosure so that it can disclose information in accordance with section 6(b) as soon as is reasonably possible after expiration of the statutory fifteen day moratorium on disclosure'' and in its place, add: ''The Commission will attempt to make its decision on disclosure so that the Commission can

disclose information in accordance with section 6(b) after expiration of the statutory 15-day prohibition on disclosure''.

B. In § 1101.31(c), remove: ''To the extent it is practical the Commission will also accompany the disclosure with any other relevant information in its possession that places the released information in context'' and in its place, add: ''The Commission also will accompany the disclosure, to the extent practicable, with any other relevant information in the Commission's possession that places the released information in context''.

13. Proposed Changes to § 1101.32 (Reasonable Steps To Assure Information Is Accurate.)

We propose the following technical changes to § 1101.32:

A. In § 1101.32(a), remove: ''it'' and in its place, add: ''that the Commission''.

B. In § 1101.32(a)(3), remove: ''it'' and in its place, add: ''the information''.

C. In § 1101.32(b), remove: ''it'' and in its place, add: ''the Commission''.

D. In § 1101.32(b)(3), remove: ''investigating its accuracy'' and in its place, add: ''investigating the accuracy of the information''.

E. In § 1101.32(b)(4), insert: ''that'' between ''accuracy of the information'' and ''the Commission proposes to disclose''.

14. Proposed Changes to § 1101.33 (Reasonable Steps To Assure Information Release Is Fair in the Circumstances.)

Currently, § 1101.33(a)(1), which provides an example of the reasonable steps the Commission will take to assure disclosure of information to the public is fair in the circumstances, states: ''The Commission will accompany information disclosed to the public with the manufacturer's or private labeler's comments unless the manufacturer or private labeler asks in its section 6(b) comments that its comments or a designated portion thereof not accompany the information.''

We propose revising the first part of this section to conform to 15 U.S.C. 2055(b). As discussed above, in § 1101.31, the Commission must include with the disclosure a firm's comments if the manufacturer or private labeler requests inclusion and inclusion is permitted by and subject to the requirements of section 6(b)(1). 15 U.S.C. 2055(b)(1). In instances where the firm does not request disclosure, the Commission has discretion in releasing a firm's comments. *Id.* To reflect the statutory language, we propose revising the first part of § 1101.33(a)(1) to state: ''To the extent permitted by and subject to the requirements of section 6(b), the Commission may accompany information disclosed to the public with the manufacturer's or private labeler's comments or other information or a summary thereof.''

In addition, we propose revising § 1101.33(a)(1) to require firms to provide a rationale for why the comments should not be disclosed and an explanation of why disclosure of the comments is not necessary to assure that the disclosure of the information is fair in the circumstances. To encourage firms to provide useful information and clarifying comments, as discussed above, in § 1101.31, we propose revising the regulation to require specific information for the Commission to consider. The second part of § 1101.33(a)(1) would state: ''unless the manufacturer or private labeler asks in the firm's section 6(b) comments that the comments or a designated portion thereof not accompany the information, provides a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed, and explains why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances. If the firm objects to the disclosure of a portion of the firm's comments, the firm must specifically identify those portions that should be withheld. Conclusory statements that comments must be withheld with no supporting basis are not sufficient to justify a request for nondisclosure.''

Incorporating the changes outlined above, proposed § 1101.33(a)(1) would state: ''To the extent permitted by and subject to the requirements of section 6(b), the Commission may accompany information disclosed to the public with the manufacturer's or private labeler's comments or other information or a summary thereof unless the manufacturer or private labeler asks in the firm's section 6(b) comments that the comments or a designated portion thereof not accompany the information, provides a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed, and explains why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances. If the firm objects to the disclosure of a portion of the firm's comments, the firm must specifically identify those portions that should be withheld. Conclusory statements that comments must be withheld with no supporting basis are not sufficient to justify a request for nondisclosure.''

Currently, § 1101.33(b)(3), which provides an example of information that would not be disclosed because the information generally would not be considered fair in the circumstances, reads: ''Disclosure of the work-product of attorneys employed by a firm and information subject to an attorney/client privilege, if the Commission has obtained the information from the client or the attorney, the attorney or client advises the Commission of the confidential nature of the information at the time it is submitted to the Commission, and the information has been maintained in confidence by the client and the attorney.''

In general, we believe that firms waive these protections when they submit information to the Commission that is attorney work-product or subject to the attorney/client privilege. Moreover, firms rarely claim in their comments to the Commission that the information proposed for disclosure contains information subject to the attorney/client privilege or the work-product doctrine. For example, in FY 2012, our FOIA office processed approximately 459 notices under section 6(b). Of those 459 notices, firms claimed attorney/client privilege and/or the work-product doctrine in only approximately 12 instances. The majority of firms that asserted this claim did not identify the specific information to which the claim pertained, but included the claim in a broad list of claims that included confidential business information and general fairness objections. For these reasons, we propose removing § 1101.33(b)(3) from the regulation.

Currently, § 1101.33(b)(4), which provides another example of information that would not be disclosed because the information generally would not be considered fair in the circumstances, reads: ''Disclosure of a firm's comments (or a portion thereof) submitted under section 6(b)(1) over the firm's objection.'' As discussed above, in § 1101.31, we propose revising the regulation to require that firms provide a rationale for why comments should not be disclosed and an explanation of why disclosure of the comments is not necessary to assure that the disclosure of the information is fair in the circumstances. In addition, because we propose removing § 1101.33(b)(3) from the regulation, we will renumber § 1101.33(b)(4) as § 1101.33(b)(3). Proposed § 1101.33(b)(3) would state: ''Disclosure of a firm's comments (or a portion thereof) submitted under section 6(b)(1) if the firm provides a rationale,

such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed and explains why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances.''

In addition, we propose the following technical corrections to § 1101.33:

A. In the second sentence of § 1101.33(a)(2), remove: ''information it its possession'' and in its place, add: ''information in its possession''.

B. In the first sentence of § 1101.33(a)(3), remove: ''it'' and in its place, add: ''the Commission''.

C. In § 1101.33(a)(3), remove: ''For example, the Commission may determine it is not appropriate to issue a nationwide press release in a particular situation and rather will issue a press release directed at certain localities, regions, or user populations'' and in its place, add: ''For example, the Commission may determine that issuance of a nationwide press release in a particular situation is not appropriate and rather will issue a press release directed at certain localities, regions or user populations''.

D. In the second sentence of § 1101.33(a)(4) add after ''information piecemeal'' the phrase: ''if such disclosure would be unfair''.

E. In § 1101.33(b)(1), remove: ''in concidence'' and in its place, add: ''in confidence''.

F. In § 1101.33(b)(2), insert: ''staff'' between ''Disclosure of'' and ''notes''.

15. Proposed Changes to § 1101.34 (Reasonable Steps To Assure Information Release Is ''Reasonably Related to Effectuating the Purposes of the Acts'' the Commission Administers.)

We propose the following technical changes to § 1101.34(a)(2):

A. Remove: ''Purposes of the FHSA, FFA, PPPA and RSA'' and in its place, add: ''Purposes of the FHSA, FFA, PPPA, RSA, CSPA, VGBA, and CGBPA''.

B. In the first sentence, insert: ''and other'' between ''transferred'' and ''acts''.

16. Proposed Changes to § 1101.41 (Generally.)

We propose the following technical changes to § 1101.41:

A. In § 1101.41(a)(4), capitalize ''information''.

B. In § 1101.41(b), remove: ''transferred act'' and in its place, add: ''transferred and other acts''.

C. In § 1101.41(b), remove: ''transferred acts'' and in its place, add: ''transferred and other acts''.

17. Proposed Changes to § 1101.42 (Imminent Hazard Exception.)

Currently, § 1101.42(b), which discusses the scope of the imminent hazard exception, reads: ''This exception applies once the Commission has filed an action under section 12 of the CPSA (15 U.S.C. 2061), in a United States district court. Once the exception applies, information may be disclosed to the public while the proceeding is pending without following the requirements of section 6(b)(1) if the information concerns or relates to the product alleged to be imminently hazardous. Upon termination of the proceeding, information filed with the court or otherwise made public is not subject to section 6(b). Information in the Commission's possession which has not been made public is subject to section 6(b).''

We propose the following revisions to § 1101.42(b):

1. In the second sentence, remove: ''while the proceeding is pending''.

2. Remove the third and fourth sentences.

We recognize that when the Commission adopted the final rule in 1983, we decided, in response to a comment, that ''documents in the Commission's possession that concern a product for which it has filed an imminent hazard action and that it has not made publicly available'' are subject to the 6(b) requirements. 48 FR 57425. We stated that ''these documents are more similar to documents prepared during the course of other Commission's activities which are routinely subject to section 6(b) and, therefore, will be treated accordingly.'' *Id.* We do not believe, however, that the statute imposes these restrictions on the Commission's release of information. Upon the Commission's filing of a section 12 action, we believe that information may be disclosed to the public during and after the proceeding, even if the information was not filed with the court or otherwise made public. Therefore, we propose deleting, ''while the proceeding is pending'', from the second sentence and removing the third and fourth sentences from § 1101.42(b).

18. Proposed Changes to § 1101.45 (Adjudicatory Proceeding Exception.)

We propose the following technical correction to § 1101.45(b):

A. Remove: ''FAA'' and in its place, add: ''FFA''.

19. Proposed Changes to § 1101.46 (Other Administrative or Judicial Proceeding Exception.)

We propose the following technical correction to § 1101.46(b)(7):

A. Remove: ''Secretary'' and in its place, add: ''Secretariat''.

20. Proposed Changes to § 1101.51 (Commission Interpretation.)

We propose the following technical corrections to § 1101.51(b):

A. In the first sentence, replace: ''it'' with ''the information'' wherever ''it'' appears.

21. Proposed Changes to § 1101.52 (Procedure for Retraction.)

We propose the following technical and conforming changes to § 1101.52:

A. In § 1101.52(a), remove the comma between ''distributor'' and ''or''.

B. In § 1101.52(b), remove: ''the Commission or an individual member, employee, agent, contractor or representative of the Commission'' and in its place, add: ''the Commission, any member of the Commission, or any employee, agent, or representative, including contractor, of the Commission in an official capacity''.

C. In § 1101.52(b), remove: ''The request must be in writing and addressed to the Secretary, CPSC. Washington, DC 20207'' and in its place, add: ''The request must be in writing and sent via either electronic mail to cpsc-os@cpsc.gov or first class mail to The Secretariat, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD, 20814–4408''.

D. In § 1101.52(c)(2), add: ''that'' between ''information'' and ''the firm''.

E. In § 1101.52(d), remove: ''the Commission or any individual member, employee, agent [sic] contractor or representative of the Commission'' and in its place, add: ''the Commission, any member of the Commission, or any employee, agent, or representative, including contractor, of the Commission in an official capacity''.

F. In § 1101.52(d), remove: ''If the Commission finds that fuller disclosure is necessary, it will publish a retraction in the manner it determines appropriate under the circumstances'' and in its place, add: ''If the Commission finds that fuller disclosure is necessary, the Commission will publish a retraction in the manner that the Commission determines appropriate under the circumstances''.

G. In § 1101.52(e), replace: ''its'' with ''the Commission's''.

22. Proposed Changes to § 1101.61 (Generally.)

We propose the following technical correction to § 1101.61(b)(3):

A. Remove the period and in its place, add: ''; or''.

23. Proposed Changes to § 1101.63 (Information Submitted Pursuant to Section 15(b) of the CPSA.)

Currently, § 1101.63(c) reads: ''Section 6(b)(5) does not apply to information independently obtained or prepared by the Commission staff.'' The legislative history indicates that in granting the Commission broad information-gathering powers, the Commission was intended to have access to section 15 information, such as trade secrets and other sensitive cost and competitive information, which would not otherwise be available to the public or to government. H.R. Rep. No. 92–1153, at 31 (1972). The apparent intent was not to protect information that the staff could identify or prepare independently from material in the public realm, but only to limit disclosure of confidential trade secret and competitive information not otherwise publicly available. *Id.*

Technological advances since enactment of the 1983 regulation merit further refinement of this exception. For example, Internet resources, which did not exist at the time of the enactment of the 1983 regulation, have significantly expanded the public availability of information about products; this public information may also be a part of a firm's section 15 report. Searching the name of a product in any Internet search engine may yield significant information about a product, including product reviews and Internet sites or retail locations where the product can be purchased. The Commission does not believe that the restriction on the disclosure of information contained in reports submitted to the Commission pursuant to section 15(b) was intended to apply to such publicly-available information. Indeed, inclusion of such information would frustrate the transparent disclosure of information if readily available information from the public domain could not be disclosed simply because a firm included such information in a section 15(b) report to the Commission. Therefore, information that a firm submits to the Commission pursuant to section 15(b) that is readily available to the public because, for example, the information appears in newspaper articles, on retailer Web sites, in product reviews, in the consumer product safety information database, or in other sources, constitutes information that is independently obtained under this provision and thus not subject to the requirements of section 6(b)(5).

Accordingly, we propose revising § 1101.63(c) to state: ''Section 6(b)(5) does not apply to information (1) independently obtained or prepared by the Commission staff or (2) identified by the Commission staff through publicly available sources. For example, information that is publicly available or that has been disseminated in a manner intended to reach the public in general, such as news reports; articles in academic and scientific journals; press releases distributed through news or wire services; information that is available on the Internet; or information appearing on the publicly available consumer product safety information database established pursuant to section 6A of the CPSA, 15 U.S.C. 2055a, does not fall within section 6(b)(5)'s disclosure limits.''

24. Proposed Changes to § 1101.71 (Delegation of Authority.)

We propose the following technical changes to § 1101.71:

A. In § 1101.71, remove: ''Secretary'' and in its place, add: ''Secretariat'' wherever ''Secretary'' appears.

B. In § 1101.71(a), remove: ''section 27(b)(9) of the CPSA 15 U.S.C. 2076(b)(9)'' and in its place, add: ''27(b)(10) of the CPSA, 15 U.S.C. 2076(b)(10),''.

C. In § 1101.71(b), remove: ''Findings not deleted'' and in its place, add: ''Findings not delegated''.

D. In § 1101.71(b)(1), insert: ''calendar'' between ''15'' and ''days''.

E. In § 1101.71(b)(2), insert: ''calendar'' between ''(5)'' and ''days''.

F. In § 1101.71(b)(2), remove the semicolon and in its place, add a period.

G. In § 1101.71(b)(3), remove: ''it'' and in its place, add: ''the Commission''.

III. Environmental Considerations

The Commission's regulations address whether the Commission is required to prepare an environmental assessment or an environmental impact statement. 16 CFR Part 1021. These regulations provide a categorical exclusion for certain CPSC actions that normally have ''little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(1). This proposed rule falls within the categorical exclusion.

IV. Regulatory Flexibility Analysis

Under section 603 of the Regulatory Flexibility Act (RFA), when the Administrative Procedure Act (APA) requires an agency to publish a general notice of proposed rulemaking, the agency must prepare an initial regulatory flexibility analysis (IFRA) assessing the economic impact of the proposed rule on small entities. 5 U.S.C. 603(a). As noted, the Commission is proposing to update the regulation that interprets section 6(b) of the CPSA. Although the Commission is choosing to issue the rule through notice and comment procedures, the APA does not require a proposed rule when an agency issues an interpretive rule. Therefore, no IRFA is required under the RFA. Moreover, the proposed rule would not establish any mandatory requirements and would not impose any obligations on small entities (or any other entity or party).

V. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) establishes certain requirements when an agency conducts or sponsors a ''collection of information.'' 44 U.S.C. 3501–3520. The proposed rule would amend the Commission's rule that describes the agency's procedures for providing manufacturers and private labelers with advance notice and ''a reasonable opportunity to submit comments'' to the Commission on proposed disclosures of product-specific information. The proposed rule would not impose any information collection requirements. The existing rule and the proposed amendment do not require or request information from firms, but rather, explain the Commission's procedures that provide an opportunity for firms to comment on product-specific information before disclosure. Thus, the PRA is not implicated in this proposed rulemaking.

VI. Executive Order 12988 (Preemption)

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. Section 26 of the CPSA explains the preemptive effect of consumer product safety standards issued under the CPSA. 15 U.S.C. 2075. The proposed rule is not a consumer product safety standard, but rather, is an interpretive rule that would interpret section 6(b) of the CPSA. Therefore, section 26 of the CPSA would not apply to this rulemaking.

VII. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). However, an earlier effective date is permitted for interpretive rules and statements of policy. *Id.* Thus, this proposed rule is excepted from the APA effective date requirement. *Id.* 553(d)(2).

Because CPSC is giving notice and soliciting comment (even though notice and comment procedures are not required), the public and potentially affected firms will have significant advance notice of the agency's proposed rule. Moreover, implementation of the rule will not result in the imposition of new, mandatory requirements on firms. Therefore, the Commission proposes that the effective date be the date of publication of a final rule in the **Federal Register**.

VIII. Request for Comments

The Commission requests comments on all aspects of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this NPR. Written comments must be received by April 28, 2014.

List of Subjects in 16 CFR Part 1101

Administrative practice and procedure; Consumer protection.

Accordingly, the Commission proposes to revise 16 CFR Part 1101 to read as follows:

PART 1101—INFORMATION DISCLOSURE UNDER SECTION 6(B) OF THE CONSUMER PRODUCT SAFETY ACT

Subpart A—Background

Sec.
1101.1 General background.
1101.2 Scope.

Subpart B—Information Subject to Notice and Analysis Provisions of Section 6(b)(1)

1101.11 General application of provisions of section 6(b)(1).
1101.12 Definition of ''public''.
1101.13 Public ability to ascertain readily identity of manufacturer or private labeler.

Subpart C—Procedure for Providing Notice and Opportunity To Comment Under Section 6(b)(1)

1101.21 Form of notice and opportunity to comment.
1101.22 Timing; request for time extensions.
1101.23 Providing less than 15 days notice before disclosing information.
1101.24 Scope of comments Commission seeks.
1101.25 Notice of intent to disclose.
1101.26 Circumstances when the Commission does not provide notice and opportunity to comment.

Subpart D—Reasonable Steps Commission Will Take To Assure Information It Discloses Is Accurate, and That Disclosure Is Fair in the Circumstances and Reasonably Related To Effectuating the Purposes of the Acts It Administers

1101.31 General requirements.
1101.32 Reasonable steps to assure information is accurate.
1101.33 Reasonable steps to assure information release is fair in the circumstances.
1101.34 Reasonable steps to assure information release is ''reasonably related to effectuating the purposes of the Acts'' the Commission administers.

Subpart E—Statutory Exceptions of Section 6(b)(4)

1101.41 Generally.
1101.42 Imminent hazard exception.
1101.43 Section 6(b)(4)(A) exception.
1101.44 Rulemaking proceeding exception.
1101.45. Adjudicatory proceeding exception.
1101.46 Other administrative or judicial proceeding exception.

Subpart F—Retraction

1101.51 Commission interpretation.
1101.52 Procedure for retraction.

Subpart G—Information Submitted Pursuant to Section 15(b) of the CPSA

1101.61 Generally.
1101.62 Statutory exceptions to section 6(b)(5) requirements.
1101.63 Information submitted pursuant to section 15(b) of the CPSA.

Subpart H—Delegation of Authority to Information Group

1101.71 Delegation of authority.

Authority: Section 6(b) of Pub. L. 92–573, as amended by Section 211 of Pub. L. 110–314, 122 Stat. 3016, 15 U.S.C. 2055(b), 5 U.S.C. 553(b).

Subpart A—Background

§ 1101.1 General background.

(a) *Basic purpose.* This part sets forth the Consumer Product Safety Commission's policy and procedure under sections 6(b)(1)–(5) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2055(b)(1)–(5)) which relate to public disclosure of information from which the identity of a manufacturer or private labeler of a product can be readily ascertained. In addition, these rules provide for retraction of inaccurate or misleading information the Commission has disclosed that reflects adversely on the safety of a consumer product or class of products or on the practices of any manufacturer, private labeler, distributor or retailer of consumer products as required by section 6(b)(7) of the CPSA (15 U.S.C. 2055(b)(7)).

(b) *Statutory requirements.* Section 6(b) establishes procedures that the Commission must follow when it releases certain firm specific information to the public and when it retracts certain information it has released.

(1) Generally, section 6(b)(1) requires the Commission to provide manufacturers or private labelers with advance notice and opportunity to comment on information the Commission proposes to release, if the public can readily ascertain the identity of the firm from the information. Section 6(b)(1) also requires the Commission to take reasonable steps to assure that the information is accurate and that disclosure is fair in the circumstances and reasonably related to effectuating the purposes of the Acts administered by the Commission. Disclosure of information may not occur in fewer than 15 calendar days after notice to the manufacturer or private labeler unless the Commission publishes a finding that the public health and safety requires a lesser period of notice. Section 6(b)(4) establishes exceptions to these requirements. Section 6(b)(5) creates additional limitations, as well as exceptions to these limitations, on the disclosure of information reported to the Commission under section 15(b) of the CPSA.

(2) Section 6(b)(2) requires the Commission to provide further notice to manufacturers or private labelers where the Commission proposes to disclose product-specific information the firms have claimed to be inaccurate.

(3) Section 6(b)(3) authorizes manufacturers and private labelers to bring lawsuits against the Commission to prevent disclosure of product-specific information after the firms have received the notice specified.

(c) *Internal clearance procedures.* Section 6(b)(6) requires the Commission to establish internal clearance procedures for Commission initiated disclosures of information that reflect on the safety of a consumer product or class of products, even if the information is not product specific. This rule does not address section 6(b)(6) because the Commission has internal clearance procedures in its directives system. (Directive 1450.2 ''Clearance Procedures for Commission Staff to Use in Providing Information to the Public.'' January 16, 2003.)

§ 1101.2 Scope.

Section 6(b) and this part apply to information obtained under the CPSA or to be disclosed to the public concerning products subject to the CPSA (15 U.S.C. 2051–2089), and to the four other acts the Commission administers (transferred acts). These transferred acts are the Flammable Fabrics Act, 15 U.S.C. 1191–1204 (FFA); the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471–1477 (PPPA); the Federal Hazardous Substances Act, 15 U.S.C. 1261–1278a (FHSA); and the

Refrigerator Safety Act, 15 U.S.C. 1211–1214 (RSA). These provisions also apply to the Child Safety Protection Act 101 and 102, Public Law 103–267, 108 Stat. 722 (June 16, 1994) (CSPA); the Virginia Graeme Baker Pool and Spa Safety Act, 15 U.S.C. 8003(a) (VGBA); and the Children's Gasoline Burn Prevention Act 2(a), Public Law 110–278, 122 Stat. 2602 (July 17, 2008) (CGBPA).

Subpart B—Information Subject to Notice and Analysis Provisions of Section 6(b)(1)

§ 1101.11 General application of provisions of section 6(b)(1).

(a) *Information subject to section 6(b)(1).* To be subject to the notice and analysis provisions of section 6(b)(1), information must meet all the following criteria:

(1) The information must pertain to a specific product.

(2) The information must be obtained under the acts the Commission administers, or be disclosed to the public in connection therewith.

(3) The Commission, any member of the Commission, or any employee, agent, or representative, including contractor, of the Commission in an official capacity must propose to disclose the information to the public (see § 1101.12).

(4) The manner in which the product is designated or described in the information must permit the public to ascertain readily the identity of the manufacturer or private labeler. [See § 1101.13.]

(b) *Information not subject to section 6(b)(1).* The requirements of section 6(b)(1) do not apply to:

(1) Information described in the exclusions contained in section 6(b)(4) or (b)(5) of the CPSA (see subpart E and G of this rule).

(2) Information the Commission is required by law to make publicly available. This information includes, for example, Commission notifications to foreign governments regarding certain products to be exported, as required by section 18(b) of the CPSA, 15 U.S.C. 2067(b); section 14(d) of the FHSA, 15 U.S.C. 1273(d); and section 15(c) of the FFA, 15 U.S.C. 1202(c). (See the Commission's Export Policy Statement, 16 CFR part 1019.)

(3) Information required to be disclosed to the President and Congress pursuant to section 27(j) of the CPSA, 15 U.S.C. 2076(j).

(4) Press releases issued by firms.

(5) Information filed or presented in administrative proceedings or litigation to which the Commission is a party and which is not expressly subject to the section 6(b)(4) exceptions.

(6) A report of harm posted on the publicly available consumer product safety information database pursuant to section 6A of the CPSA, 15 U.S.C. 2055a.

(7) Information that is publicly available or that has been disseminated in a manner intended to reach the public in general, such as news reports; articles in academic and scientific journals; press releases distributed through news or wire services; or information that is available on the Internet.

(8) Information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1), except as specified in § 1101.31(d).

§ 1101.12 Definition of "public".

Public. For the purposes of section 6(b)(1), the public includes any person except:

(a) Any member of the Commission or any employee, agent, or representative, including contractor, of the Commission in an official capacity.

(b) State officials who are commissioned officers under section 29(a)(2) of the CPSA, 15 U.S.C. 2078(a)(2), to the extent that the Commission furnishes them information necessary for them to perform their duties under that section. Such officials may not release to the public copies of such information unless the Commission has complied with section 6(b) or the information falls within an exception to section 6(b).

(c) Members of a Commission Chronic Hazard Advisory Panel established under section 28 of the CPSA (15 U.S.C. 2077). However, disclosures of information by such a Panel are subject to section 6(b).

(d) The persons or firms to which the information to be disclosed pertains, or their legal representatives.

(e) The persons or firms who provided the information to the Commission, or their legal representatives.

(f) Other federal agencies or state or local governments to which accident and investigation reports are provided pursuant to section 29(e) of the CPSA (15 U.S.C. 2078(e)). However, as required by that section, employees of federal agencies or state or local governments may not release to the public copies of any accident or investigation report made under the CPSA by an officer, employee or agent of the Commission unless CPSC has complied with the applicable requirements of section 6(b).

(g) The Chairman or ranking minority member of a committee or subcommittee of Congress acting pursuant to committee business and having jurisdiction over the matter which is the subject of the information requested.

(h) Any federal, state, local, or foreign government agency pursuant to, and in accordance with, section 29(f) of the Consumer Product Safety Improvement Act of 2008 (Pub. L. 110–314, 122 Stat. 3016 (August 14, 2008)).

§ 1101.13 Public ability to ascertain readily identity of manufacturer or private labeler.

The advance notice and analysis provisions of section 6(b)(1) apply only when a reasonable person receiving the information in the form in which the information is to be disclosed and lacking specialized expertise can readily ascertain from the information itself the identity of the manufacturer or private labeler of a particular product.

Subpart C—Procedure for Providing Notice and Opportunity To Comment Under Section 6(b)(1)

§ 1101.21 Form of notice and opportunity to comment.

(a) *Notice may be oral or written.* (1) The Commission will generally provide to manufacturers or private labelers written notice and opportunity to comment on information subject to section 6(b)(1). Whenever possible, the Commission will transmit such notice electronically. However, when the Commission publishes a finding that the public health and safety requires a lesser period of notice pursuant to section 6(b)(1) of the CPSA, the Commission may determine that notice and opportunity to comment orally is necessary.

(2) Any notice required to be given under the provisions of this Part 1101 may be transmitted using electronic means of communication. Whenever possible, the Commission will transmit such notice electronically.

(b) *Content of notice.* The Commission shall, to the extent practicable, provide the manufacturer or private labeler with:

(1) Either the actual text of the information to be disclosed or, if appropriate, a summary of the information.

(2) A general description of the manner in which the Commission will disclose the information, including any other relevant information the Commission intends to include with the disclosure. If the Commission advises that the form of disclosure will be by press release, for example, the Commission need not provide further notice to disclose a summary of the press release.

(3) A request for comment with respect to the information, including a request for explanatory data or other relevant information for the Commission's consideration.

(4) A statement that, in the absence of a specific request by a firm that its comments be withheld from disclosure, the Commission will release to the public the firm's comments (or a summary thereof prepared by the firm or, if the firm declines to do so, by the Commission).

(5) A statement that if the manufacturer or private labeler objects to disclosure of its comments or a portion thereof, the manufacturer or private labeler must notify the Commission of such objection at the time the manufacturer or private labeler submits its comments, provide a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed, and explain why disclosure of the comments is not fair in the circumstances or is not reasonably related to effectuating the purposes of the CPSA.

(6) Notice that the firm may request confidential treatment for the information, in accordance with section 6(a)(3) of the Consumer Product Safety Act, 15 U.S.C. 2055(a)(3) (see § 1101.24(b)).

(7) A statement that no further request for comment will be sought by the Commission if the Commission intends to disclose information that is substantially the same as the information that the Commission previously disclosed.

(8) The name, address, applicable contact information for electronic communication, and telephone number of the person to whom comments should be sent and the time when any comments are due (see § 1101.22).

§ 1101.22 Timing: request for time extensions.

(a) *Time for comment.* (1) In the interest of promoting timely notification, the Commission, whenever possible, will transmit electronically to the manufacturer or private labeler the notice to furnish comments to the Commission. Generally firms will receive ten (10) calendar days from the date of such notice. Firms that receive notice by mail will receive an additional three (3) calendar days to comment to account for time in the mail.

(2) Upon request, the Freedom of Information Officer may provide a different amount of time for comment, particularly for firms that receive voluminous or complex material. In addition, the Commission may publish a finding that the public health and safety requires a lesser period of notice and may require a response in a shorter period of time (see § 1101.23).

(b) *No response submitted.* (1) If the Commission has not received a response within the time specified and has received no request for extension of time, the Commission will analyze the information as provided in subpart D of this part. If no comments are submitted, the Commission will not give the further notice provided in section 6(b)(2).

(2) The Commission will not disclose the information in fewer than 15 calendar days after providing a manufacturer or private labeler with notice and an opportunity to comment, unless (i) the firm agrees to a lesser period or does not object to disclosure, or (ii) the Commission publishes a finding that the public health and safety requires a lesser period of notice (see § 1101.23).

(c) *Requests for time extension.* (1) Requests for extension of time to comment on information to be disclosed must be made to the person who provided the Commission's notice and opportunity to comment. The request for time extension may be either oral or written. An oral request for a time extension must be promptly confirmed in writing.

(2) Requests for extension of time must explain with specificity why the extension is needed and how much additional time is required.

(3) The Commission will promptly respond to requests for extension of time.

§ 1101.23 Providing less than 15 days notice before disclosing information.

There are two circumstances in which the Commission may disclose to the public information subject to section 6(b)(1) in a time less than 15 calendar days after providing notice to the manufacturer or private labeler.

(a) *Firm agrees to lesser period or does not object to disclosure.* The Commission may disclose to the public information subject to section 6(b)(1) before the 15-day period expires when, after receiving the Commission's notice and opportunity to comment, the firm involved agrees to the earlier disclosure; notifies the Commission that the firm has no comment; or notifies the Commission that the firm does not object to disclosure.

(b) *Commission finding a lesser period is required.* Section 6(b)(1) provides that the Commission may publish a finding that the public health and safety requires a lesser period of notice than the 15 calendar days advance notice that section 6(b)(1) generally requires. The Commission may find that the public health and safety requires less than 15 calendar days advance notice, for example, to warn the public quickly because individuals may be in danger from a product hazard or a potential hazard, or to correct product safety information released by third persons, which mischaracterizes statements made by the Commission about the product or which attributes to the Commission statements about the product which the Commission did not make.

(c) *Notice of finding.* The Commission will inform a manufacturer or private labeler of a product which is the subject of a public health and safety finding that the public health and safety requires less than 15 calendar days advance notice either orally or in writing, depending on the immediacy of the need for quick action. If written notice is provided, the Commission, whenever possible, will transmit such notice electronically. Before releasing information, the Commission will comply with the requirements of section 6(b)(1) and (2) by giving the firm the opportunity to comment on the information, either orally or in writing depending on the immediacy of the need for quick action, and by giving the firm advance notice before disclosing information claimed by a manufacturer or private labeler to be inaccurate (see § 1101.25).

§ 1101.24 Scope of comments Commission seeks.

(a) *Comment in regard to the information.* The section 6(b) opportunity to comment on information is intended to permit firms to furnish information and data to the Commission to assist the agency in its evaluation of the accuracy of the information. A firm's submission, therefore, must be specific and should be accompanied by documentation, where available, if the comments are to assist the Commission in its evaluation of the information. Comments of a general nature, such as general suggestions or allegations that a document is inaccurate or that the Commission has not taken reasonable steps to assure accuracy, are not sufficient to assist the Commission in its evaluation of the information or to justify a claim of inaccuracy. The weight accorded a firm's comments on the accuracy of information and the degree of scrutiny which the Commission will exercise in evaluating the information will depend on the specificity and completeness of the firm's comments and of the accompanying documentation. In general, specific comments which are accompanied by

documentation will be given more weight than those which are undocumented and general in nature.

(b) *Claims of confidentiality.* If the manufacturer or private labeler believes the information involved cannot be disclosed because of section 6(a)(2) of the CPSA (15 U.S.C. 2055(a)(2)), which refers to trade secret or other confidential material and information subject to 5 U.S.C. 552(b)(4), the firm may make claims of confidentiality at the time it submits its comments to the Commission under this section. Such claims must identify the specific information which the firm believes to be confidential or trade secret material or subject to 5 U.S.C. 552(b)(4) and must state with specificity the grounds on which the firm bases its claims. (See Commission's Freedom of Information Act regulation, 16 CFR part 1015, particularly 16 CFR 1015.18.)

(c) *Requests for nondisclosure of comments.* If a firm objects to disclosure of its comments or a portion thereof, the firm must notify the Commission of such objection at the time the firm submits its comments, provide a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed, and explain why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances. If the firm objects to the disclosure of a portion of its comments, the firm must specifically identify those portions that should be withheld. Conclusory statements that comments must be withheld with no supporting basis are not sufficient to justify a request for nondisclosure.

§ 1101.25 Notice of intent to disclose.

(a) *Notice to manufacturer or private labeler.* In accordance with section 6(b)(2) of the CPSA, if the Commission, after following the notice provisions of section 6(b)(1), determines that information claimed to be inaccurate by a manufacturer or private labeler in comments submitted under section 6(b)(1) should be disclosed because the Commission believes it has complied with section 6(b)(1), the Commission shall notify the manufacturer or private labeler that the Commission intends to disclose the information not less than five (5) calendar days after the date of the receipt of notification by the firm. The notice of intent to disclose will include an explanation of the reason for the Commission's decision and copies of any additional materials, such as explanatory statements and letters to Freedom of Information Act requesters, which were not previously sent to the firm.

(b) *Commission finding a lesser period is required.* The Commission may determine that the public health and safety requires less than five (5) calendar days advance notice of the Commission's intent to disclose information claimed to be inaccurate. For example, the Commission may determine that the public must be warned more quickly than five (5) calendar days because of danger from a product hazard or a potential hazard, or to correct product safety information released by third persons, which mischaracterizes statements made by the Commission about the product or which inaccurately attributes to the Commission statements about the product.

(c) *Notice of findings.* The Commission will inform a manufacturer or private labeler of a product that is the subject of a public health and safety finding that the public health and safety requires less than five (5) calendar days advance notice either orally or in writing, depending on the immediacy of the need for quick action. If written notice is provided, the Commission, whenever possible, will transmit such notice electronically.

§ 1101.26 Circumstances when the Commission does not provide notice and opportunity to comment.

(a) *Notice to the extent practicable.* Section 6(b)(1) requires that ''to the extent practicable'' the Commission must provide manufacturers and private labelers notice and opportunity to comment before disclosing information from which the public can ascertain readily their identity.

(b) *Circumstances when notice and opportunity to comment is not practicable.* The Commission has determined that there are various circumstances when notice and opportunity to comment is not practicable. Examples include the following:

(1) When the Commission has taken reasonable steps to assure that the company to which the information pertains is out of business and has no identifiable successor.

(2) When the information is disclosed in testimony in response to an order of the court during litigation to which the Commission is not a party.

Subpart D—Reasonable Steps Commission Will Take To Assure Information It Discloses Is Accurate, and That Disclosure Is Fair in the Circumstances and Reasonably Related to Effectuating the Purposes of the Acts It Administers

§ 1101.31 General requirements.

(a) *Timing of decisions.* The Commission will attempt to make its decision on disclosure so that the Commission can disclose information in accordance with section 6(b) after expiration of the statutory 15-day prohibition on disclosure.

(b) *Inclusion of comments.* In disclosing any information under this section, the Commission may, and upon the request of the manufacturer or private labeler shall, include any comments or other information or a summary thereof submitted by the manufacturer or private labeler to the extent permitted by and subject to the requirements of section 6(b). If the manufacturer or private labeler, at the time it submits its section 6(b) comments, specifically requests that the Commission not include the comments, or include only a designated portion of the comments, the manufacturer or private labeler must provide for evaluation by the Commission, a rationale, such as an applicable statutory or regulatory basis or provision, supporting such withholding and an explanation of why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances.

(c) *Explanatory statements.* Where appropriate, the Commission will accompany the disclosure of information subject to this subpart with an explanatory statement that makes the nature of the information disclosed clear to the public. Inclusion of an explanatory statement is in addition to, and not a substitute for, taking reasonable steps to assure the accuracy of information. The Commission also will accompany the disclosure, to the extent practicable, with any other relevant information in the Commission's possession that places the released information in context.

(d) *Information previously disclosed.* If the Commission intends to disclose information that is substantially the same as information that the Commission previously disclosed in accordance with section 6(b)(1), the Commission is not obligated to take any additional steps to assure accuracy unless the Commission has reason to question the accuracy of the information.

§ 1101.32 Reasonable steps to assure information is accurate.

(a) The Commission considers that the following types of actions are reasonable steps to assure the accuracy of information that the Commission proposes to release to the public:

(1) The Commission staff or a qualified person or entity outside the Commission (e.g., someone with requisite training or experience, such as a fire marshal, a fire investigator, an electrical engineer, or an attending physician) conducts an investigation or an inspection which yields or corroborates the product information to be disclosed; or

(2) The Commission staff conducts a technical, scientific, or other evaluation which yields or corroborates the product information to be disclosed or the staff obtains a copy of such an evaluation conducted by a qualified person or entity; or

(3) The Commission staff provides the information to be disclosed to the person who submitted the information to the Commission for review and, if necessary, correction, and the submitter confirms the information as accurate to the best of the submitter's knowledge and belief, provided that:

(i) The confirmation is made by the person injured or nearly injured in an incident involving the product; or

(ii) The confirmation is made by a person who, on the basis of his or her own observation or experience, identifies an alleged safety-related defect in or problem with such a product even though no incident or injury associated with the defect or problem may have occurred; or

(iii) The confirmation is made by an eyewitness to an injury or safety-related incident involving such a product; or

(iv) The confirmation is made by an individual with requisite training or experience who has investigated and/or determined the cause of deaths, injuries or safety-related incidents involving such a product. Such persons would include, for example, a fire marshal, a fire investigator, an electrical engineer, an ambulance attendant, or an attending physician; or

(v) The confirmation is made by a parent or guardian of a child involved in an incident involving such a product, or by a person to whom a child is entrusted on a temporary basis.

(b) The steps set forth below are the steps the Commission will take to analyze the accuracy of information which the Commission proposes to release to the public.

(1) The Commission will review each proposed disclosure of information which is susceptible of factual verification to assure that reasonable steps have been taken to assure accuracy in accordance with § 1101.32(a).

(2) As described in subpart C of this part, the Commission will provide a manufacturer or private labeler with a summary or text of the information the Commission proposes to disclose and will invite comment with respect to that information.

(3) If the Commission receives no comments or only general, undocumented comments claiming inaccuracy, the Commission will review the information in accordance with paragraph (a) of this section and release it, generally without further investigating the accuracy of the information if there is nothing on the face of the information that calls its accuracy into question.

(4) If a firm comments on the accuracy of the information that the Commission proposes to disclose, the Commission will review the information in light of the comments. The degree of review by the Commission and the weight accorded a firm's comments will be directly related to the specificity and completeness of the firm's comments on accuracy and the accompanying documentation. Documented comments will be given more weight than undocumented comments. Specific comments will be given more weight than general comments. Further steps may be taken to determine the accuracy of the information if the Commission determines such action appropriate.

§ 1101.33 Reasonable steps to assure information release is fair in the circumstances.

(a) The steps set forth below are the steps the Commission has determined are reasonable to take to assure disclosure of information to the public is fair in the circumstances:

(1) To the extent permitted by and subject to the requirements of section 6(b), the Commission may accompany information disclosed to the public with the manufacturer's or private labeler's comments or other information or a summary thereof unless the manufacturer or private labeler asks in the firm's section 6(b) comments that the comments or a designated portion thereof not accompany the information, provides a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed, and explains why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances. If the firm objects to the disclosure of a portion of the firm's comments, the firm must specifically identify those portions that should be withheld. Conclusory statements that comments must be withheld with no supporting basis are not sufficient to justify a request for nondisclosure.

(2) The Commission generally will accompany the disclosure of information with an explanatory statement that makes the nature of the information disclosed clear to the public. The Commission will also take reasonable steps to disclose any other relevant information in its possession that will assure disclosure is fair in the circumstances.

(3) The Commission will limit the form of disclosure to that which the Commission considers appropriate in the circumstances. For example, the Commission may determine that issuance of a nationwide press release in a particular situation is not appropriate and rather will issue a press release directed at certain localities, regions or user populations.

(4) The Commission may delay disclosure of information in some circumstances. For example, the Commission may elect to postpone an information release until an investigation, analysis or test of a product is complete, rather than releasing information piecemeal if such disclosure would be unfair.

(b) The Commission will not disclose information when it determines that disclosure would not be fair in the circumstances. The following are examples of disclosures which generally would not be fair in the circumstances.

(1) Disclosure of information furnished by a firm to facilitate prompt remedial action or settlement of a case when the firm has a reasonable expectation that the information will be maintained by the Commission in confidence.

(2) Disclosure of staff notes or minutes of meetings to discuss or negotiate settlement agreements and of drafts of documents prepared during settlement negotiations, where the firm has a reasonable expectation that such written materials will be maintained by the Commission in confidence.

(3) Disclosure of a firm's comments (or a portion thereof) submitted under section 6(b)(1) if the firm provides a rationale, such as an applicable statutory or regulatory basis or provision, for why the comments should not be disclosed and explains why disclosure of the comments is not necessary to assure that the disclosure of the information that is the subject of the comments is fair in the circumstances.

§ 1101.34 Reasonable steps to assure information release is ''reasonably related to effectuating the purposes of the Acts'' the Commission administers.

(a) The steps set forth below are the steps the Commission has determined are reasonable to take to assure that the disclosure of information to the public effectuates the purposes of the Acts it administers.

(1) *Purposes of the CPSA.* The Commission will review information to determine whether disclosure would be reasonably related to effectuating one or more of the specific purposes of the CPSA, as set forth in sections 2(b) and 5, 15 U.S.C. 2051(b) and 2054.

(2) *Purposes of the FHSA, FFA, PPPA, RSA, CSPA, VGBA, and CGBPA.* The Commission will also review information concerning products subject to the transferred and other acts it administers and to the Commission's specific functions under those acts to determine whether disclosure of information would be reasonably related to effectuating the purposes of those acts.

(3) *Purposes of the FOIA.* FOIA requests will be reviewed to determine whether disclosure of the information is reasonably related to effectuating one or more of the purposes of the acts administered by the Commission. In the event of a close question on this issue, the Commission will defer to the purposes of the FOIA. The FOIA establishes a general right of the public to have access to information in the Commission's possession, particularly information that reveals whether the Commission is meeting its statutory responsibilities or information upon which the Commission bases a decision that affects the public health and safety.

(b) In reviewing proposed information disclosures, the Commission will consider disclosing the material on the basis of whether release of the information, when taken as a whole, was prepared or is maintained in the course of or to support an activity of the Commission designed to accomplish one or more of the statutory purposes.

Subpart E—Statutory Exceptions of Section 6(b)(4)

§ 1101.41 Generally.

(a) *Scope.* This subpart describes and interprets the exceptions to the requirements of section 6(b)(1)–(b)(3) that are set forth in section 6(b)(4). These exceptions apply to:

(1) Information about a product reasonably related to the subject matter of an imminent hazard action in federal court;

(2) Information about a product which the Commission has reasonable cause to believe is in violation of any consumer product safety rule or provision under the Consumer Product Safety Act (15 U.S.C. 2051, et seq.) or similar rule or provision of any other act enforced by the Commission;

(3) Information in the course of or concerning a rulemaking proceeding; or

(4) Information in the course of or concerning an adjudicatory, administrative or judicial proceeding.

(b) *Application to transferred and other acts.* The Commission will apply the exceptions contained in section 6(b)(4) to those provisions in the transferred and other acts, comparable to the specific provisions in the CPSA to which section 6(b)(4) applies.

§ 1101.42 Imminent hazard exception.

(a) *Statutory provision.* Section 6(b)(4)(A) provides that the requirements of section 6(b)(1) do not apply to public disclosure of ''information about any consumer product with respect to which product the Commission has filed an action under section 12 (relating to imminently hazardous products).''

(b) *Scope of exception.* This exception applies once the Commission has filed an action under section 12 of the CPSA (15 U.S.C. 2061), in a United States district court. Once the exception applies, information may be disclosed to the public without following the requirements of section 6(b)(1) if the information concerns or relates to the product alleged to be imminently hazardous.

§ 1101.43 Section 6(b)(4)(A) exception.

(a) *Statutory provision.* Section (6)(b)(4)(A) provides that the requirements of section 6(b)(1) do not apply to public disclosure of information about any consumer product which the Commission has reasonable cause to believe is in violation of any consumer product safety rule or provision under the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) or similar rule or provision of any other act enforced by the Commission.

(b) *Scope of exception.* This exception applies once the Commission has ''reasonable cause to believe'' there has occurred a violation of any consumer product safety rule or provision under the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) or similar rule or provision of any other act enforced by the Commission. Once the exception applies, the Commission may disclose information to the public without following the requirements of section 6(b)(1) if the information concerning the product is reasonably related to the violation.

§ 1101.44 Rulemaking proceeding exception.

(a) *Statutory provision.* Section 6(b)(4)(B) provides that the requirements of section 6(b)(1) do not apply to public disclosure of information ''in the course of or concerning a rulemaking proceeding (which shall commence upon the publication of an advance notice of proposed rulemaking or a notice of proposed rulemaking) * * * under this Act.''

(b) *Scope of exception.* This exception applies upon publication in the **Federal Register** of an advance notice of proposed rulemaking or, if no advance notice of proposed rulemaking is issued, upon publication in the **Federal Register** of a notice of proposed rulemaking, under any of the acts the Commission administers. Once the exception applies, the Commission may publicly disclose information in the course of the rulemaking proceeding which is presented during the proceeding or which is contained or referenced in the public record of the proceeding and or which concerns the proceeding without following the requirements of section 6(b)(1). Documentation supporting the public record is also excepted from section 6(b). A rulemaking proceeding includes a proceeding either to issue, to amend, or to revoke a rule.

(c) The phrase ''in the course of'' refers to information disclosed as part of the proceeding and may, therefore, include information generated before the proceeding began and later presented as part of the proceeding. A rulemaking proceeding ends once the Commission has published the final rule or a notice of termination of the rulemaking in the **Federal Register**.

(d) The phrase ''concerning'' refers to information about the proceeding itself both after the proceeding has begun and indefinitely thereafter. Therefore, the Commission may publicly disclose information that describes the substance, process and outcome of the proceeding. By issuing opinions and public statements, the Commissioners, and the presiding official, who act as decisionmakers, may also publicly explain their individual votes and any decision rendered.

§ 1101.45 Adjudicatory proceeding exception.

(a) *Statutory provision.* Section 6(b)(4)(B) provides that the requirements of section 6(b)(1) do not apply to public disclosure of

''information in the course of or concerning * * * [an] adjudicatory proceeding * * * under this Act.''

(b) *Scope of exception.* This exception applies once the Commission begins an administrative adjudication under the CPSA. The Commission will also apply the exception to any administrative adjudicatory proceeding under FHSA, FFA, or PPPA. An adjudicatory proceeding begins with the filing of a complaint under section 15 (c) or (d), 17(a) (1) or (3), or 20 of the CPSA (15 U.S.C. 2064 (c) or (d), 2066 (a) (1), or (3), or 2069); section 15 of the FHSA (15 U.S.C. 1274); section 5(b) of the FFA, (15 U.S.C. 1194(b)); or section 4(c) of the PPPA (15 U.S.C. 1473(c)). An adjudicatory proceeding ends when the Commission issues a final order, 16 CFR 1025.51–1025.58.

(c) The phrase ''in the course of'' refers to information disclosed as part of the adjudication, whether in documents filed or exchanged during discovery, or in testimony given in such proceedings, and may therefore, include information generated before the adjudication began.

(d) The phrase ''concerning'' refers to information about the administrative adjudication itself, both once it begins and indefinitely thereafter. Therefore, the Commission may publicly disclose information that describes the substance, process and outcome of the proceeding including, for example, the effectiveness of any corrective action such as information on the number of products corrected as a result of a remedial action. By issuing opinions and public statements, the Commissioners and the presiding official, who act as decisionmakers, may publicly explain their individual votes and any decision rendered.

§ 1101.46 Other administrative or judicial proceeding exception.

(a) *Statutory provision.* Section 6(b)(4)(B) provides that the requirements of section 6(b)(1) do not apply to public disclosure of ''information in the course of or concerning any . . . other administrative or judicial proceeding under this Act.''

(b) *Scope of exception.* This exception applies to an administrative or judicial proceeding, other than a rulemaking or administrative adjudicatory proceeding, under the CPSA, FHSA, FFA, or PPPA. Proceedings within this exception include:

(1) A proceeding to act on a petition to start a rulemaking proceeding. This proceeding begins with the filing of a petition and ends when the petition is denied or, if granted, when the rulemaking proceeding begins. Information subject to the exception for petition proceedings is the petition itself and the supporting documentation, and information subsequently compiled by the staff and incorporated or referenced in the staff briefing papers for and recommendation to the Commission.

(2) A proceeding to act on a request for exemption from a rule or regulation. This proceeding begins with the filing of a request for exemption and ends when the request is denied or, if granted, when the Commission takes the first step to implement the exemption, e.g., when an amendment to the rule or regulation is proposed.

(3) A proceeding to issue a subpoena or general or special order. This proceeding begins with a staff request to the Commission to issue a subpoena or general or special order and ends once the request is granted or denied.

(4) A proceeding to act on a motion to quash or to limit a subpoena or general or special order. This proceeding begins with the filing with the Commission of a motion to quash or to limit and ends when the motion is granted or denied.

(5) Any judicial proceeding to which the Commission is a party. This proceeding begins when a complaint is filed and ends when a final decision (including appeal) is rendered with respect to the Commission.

(6) Any administrative proceeding to which the Commission is a party, such as an administrative proceeding before the Merit Systems Protection Board or the Federal Labor Relations Authority. This proceeding begins and ends in accordance with the applicable regulations or procedures of the administrative body before which the proceeding is heard.

(7) A proceeding to obtain a retraction from the Commission pursuant to subpart F of these rules. This proceeding begins with the filing with the Secretariat of the Commission of a request for retraction and ends when the request is denied or, if granted, when the information is retracted.

(c) In the course of or concerning. The phrase ''in the course of or concerning'' shall have the same meaning as set forth in either § 1101.44 (c) and (d) or § 1101.45 (c) and (d), whichever is applicable.

Subpart F—Retraction

§ 1101.51 Commission interpretation.

(a) *Statutory provisions.* Section 6(b)(7) of the CPSA provides: If the Commission finds that, in the administration of this Act, it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product or class of consumer products, or the practices of any manufacturer, private labeler, distributor, or retailer of consumer products, it shall, in a manner equivalent to that in which such disclosure was made, take reasonable steps to publish a retraction of such inaccurate or misleading information.

(b) *Scope.* Section 6(b)(7) applies to inaccurate or misleading information only if the information is adverse—i.e., if the information reflects adversely either on the safety of a consumer product or on the practices of a manufacturer, private labeler, distributor or retailer. In addition, the Commission will apply section 6(b)(7) to information about products, and about manufacturers and private labelers of products, the Commission may regulate under any of the statutes it administers. Section 6(b)(7) applies to information already disclosed by the Commission, members of the Commission, or the Commission employees, agents, contractors or representatives in their official capacities.

§ 1101.52 Procedure for retraction.

(a) *Initiative.* The Commission may retract information under section 6(b)(7) on the initiative of the Commission, upon the request of a manufacturer, private labeler, distributor or retailer of a consumer product, or upon the request of any other person in accordance with the procedures provided in this section.

(b) *Request for retraction.* Any manufacturer, private labeler, distributor or retailer of a consumer product or any other person may request a retraction if he/she believes the Commission, any member of the Commission, or any employee, agent, or representative, including contractor, of the Commission in an official capacity has made public disclosure of inaccurate or misleading information, which reflects adversely either on the safety of a product with which the firm deals or on the practices of the firm. The request must be in writing and sent via either electronic mail to *cpsc-os@cpsc.gov* or first class mail to The Secretariat, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD, 20814–4408.

(c) *Content of request.* A request for retraction must include the following information to the extent it is reasonably available:

(1) The information disclosed for which retraction is requested, the date on which the information was disclosed, the manner in which it was

disclosed, who disclosed it, the type of document (e.g., letter, memorandum, news release) and any other relevant information the firm has to assist the Commission in identifying the information. A photocopy of the disclosure should accompany the request.

(2) A statement of the specific aspects of the information that the firm believes are inaccurate or misleading and reflect adversely either on the safety of a consumer product with which the firm deals or on the firm's practices.

(3) A statement of the reasons the firm believes the information is inaccurate or misleading and reflects adversely either on the safety of a consumer product with which the firm deals or on the firm's practices.

(4) A statement of the action the firm requests the Commission to take in publishing a retraction in a manner equivalent to that in which disclosure was made.

(5) Any additional data or information the firm believes is relevant.

(d) *Commission action on request.* The Commission will act expeditiously on any request for retraction within 30 working days unless the Commission determines, for good cause, that a longer time period is appropriate. If the Commission finds that the Commission, any member of the Commission, or any employee, agent, or representative, including contractor, of the Commission in an official capacity has made public disclosure of inaccurate or misleading information that reflects adversely either on the safety of the firm's product or the practices of the firm, the Commission will publish a retraction of information in a manner equivalent to that in which the disclosure was made. If the Commission finds that fuller disclosure is necessary, the Commission will publish a retraction in the manner that the Commission determines appropriate under the circumstances.

(e) *Notification to requester.* The Commission will promptly notify the requester in writing of the Commission's decision on request for retraction. Notification shall set forth the reasons for the Commission's decision.

Subpart G—Information Submitted Pursuant to Section 15(b) of the CPSA

§ 1101.61 Generally.

(a) *Generally.* In addition to the requirements of section 6(b)(1), section 6(b)(5) of the CPSA imposes further limitations on the disclosure of information submitted to the Commission pursuant to section 15(b) of the CPSA, 15 U.S.C. 2064(b).

(b) *Criteria for disclosure.* Under section 6(b)(5) the Commission shall not disclose to the public information which is identified as being submitted pursuant to section 15(b) or which is treated by the Commission staff as being submitted pursuant to section 15(b). Section 6(b)(5) also applies to information voluntarily submitted after a firm's initial report to assist the Commission in its evaluation of the section 15 report. However, the Commission may disclose information submitted pursuant to section 15(b) in accordance with section 6(b)(1)–(3) if:

(1) The Commission has issued a complaint under section 15 (c) or (d) of the CPSA alleging that such product presents a substantial product hazard; or

(2) In lieu of proceeding against such product under section 15 (c) or (d), the Commission has accepted in writing a remedial settlement agreement dealing with such product; or

(3) The person who submitted the information under section 15(b) agrees to its public disclosure; or

(4) The Commission publishes a finding that the public health and safety requires public disclosure with a lesser period of notice than is required by section 6(b)(1).

§ 1101.62 Statutory exceptions to section 6(b)(5) requirements.

(a) *Scope.* The limitations established by section 6(b)(5) do not apply to the public disclosure of:

(1) Information with respect to a consumer product which is the subject of an action brought under section 12 (see § 1101.42);

(2) Information with respect to a consumer product which the Commission has reasonable cause to believe is in violation of any consumer product safety rule or provision under the Consumer Product Safety Act (Pub. L. 92–573, 86 Stat. 1207, as amended (15 U.S.C. 2051, et seq.)) or similar rule or provision of any other act enforced by the Commission; or

(3) Information in the course of or concerning a judicial proceeding (see § 1101.45).

(b) [Reserved]

§ 1101.63 Information submitted pursuant to section 15(b) of the CPSA.

(a) Section 6(b)(5) applies only to information provided to the Commission by a manufacturer, distributor, or retailer which is identified by the manufacturer, distributor or retailer, or treated by the Commission staff as being submitted pursuant to section 15(b).

(b) Section 6(b)(5)'s limitation also applies to the portions of staff generated documents that contain, summarize or analyze such information submitted pursuant to section 15(b).

(c) Section 6(b)(5) does not apply to information (1) independently obtained or prepared by the Commission staff or (2) identified by the Commission staff through publicly available sources. For example, information that is publicly available or that has been disseminated in a manner intended to reach the public in general, such as news reports; articles in academic and scientific journals; press releases distributed through news or wire services; information that is available on the Internet; or information appearing on the publicly available consumer product safety information database established pursuant to section 6A of the CPSA, 15 U.S.C. 2055a, does not fall within section 6(b)(5)'s disclosure limits.

Subpart H—Delegation of Authority to Information Group

§ 1101.71 Delegation of authority.

(a) *Delegation.* Pursuant to section 27(b)(10) of the CPSA, 15 U.S.C. 2076(b)(10), the Commission delegates to the General Counsel or his or her senior staff designees, the authority to render all decisions under this part concerning the release of information subject to section 6(b) when firms have furnished section 6(b) comment except as provided in paragraph (b). The Commission also delegates to the Secretariat of the Commission, or his or her senior staff designee, authority to make all decisions under this part concerning the release of information under section 6(b) when firms have failed to furnish section 6(b) comment or have consented to disclosure except as provided in paragraph (b) of this section. The General Counsel shall have authority to establish an Information Group composed of the General Counsel and the Secretariat of the Commission or their designees who shall be senior staff members.

(b) *Findings not delegated.* The Commission does not delegate its authority—

(1) To find, pursuant to section 6(b)(1) and § 1101.23(b) of this part, that the public health and safety requires less than 15 calendar days advance notice of proposed disclosures of information.

(2) To find, pursuant to section 6(b)(2) and § 1101.25(b) of this part, that the public health and safety requires less than five (5) calendar days advance notice of its intent to disclose information claimed to be inaccurate.

(3) To decide whether the Commission should take reasonable steps to publish a retraction of

information in accordance with section 6(b)(7) and § 1101.52 of this part.

(c) Final agency action; Commission decision. A decision of the General Counsel or the Secretariat or their designees shall be a final agency decision and shall not be appealable as of right to the Commission. However, the General Counsel or the Secretariat may in his or her discretion refer an issue to the Commission for decision.

Dated: February 14, 2014.

Todd A. Stevenson,

Secretariat, Consumer Product Safety Commission.

[FR Doc. 2014–03600 Filed 2–25–14; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2007–0082]

RIN 0960–AG71

Revised Medical Criteria for Evaluating Human Immunodeficiency Virus (HIV) Infection and for Evaluating Functional Limitations in Immune System Disorders

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving human immunodeficiency virus (HIV) infection in adults and children under titles II and XVI of the Social Security Act (Act). We also propose to revise the introductory text of the listings that we use to evaluate functional limitations resulting from immune system disorders. The proposed revisions reflect our program experience, advances in medical knowledge, recommendations from a commissioned report and comments from medical experts and the public.

DATES: To ensure that your comments are considered, we must receive them by no later than April 28, 2014.

ADDRESSES: You may submit comments by any one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2007–0082 so that we may associate your comments with the correct regulation.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. Internet: We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov*. Use the *Search* function to find docket number SSA–2007–0082. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. Fax: Fax comments to (410) 966–2830.

3. Mail: Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl Williams, Office of Medical Listings Improvement, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Why are we proposing to revise the listings for evaluating HIV infection?

We have not comprehensively revised the HIV infection listings, 14.08 for adults and 114.08 for children, since we first published final rules for them on July 2, 1993.[1] Although we published final rules for immune system disorders on March 18, 2008 that included changes to listings 14.08 and 114.08, the criteria in the current HIV infection listings are not substantively different from the criteria in the final rules we published in 1993.[2]

What revisions are we proposing?

We propose to:

- Revise and expand the introductory text for evaluating HIV infection for both adults (section 14.00) and children (section 114.00);
- Revise the introductory text for evaluating functional limitations resulting from immune system disorders for adults (section 14.00);
- Remove current HIV infection listings 14.08A–J for adults;
- Add HIV infection listings 14.11A–H for adults;
- Redesignate and revise current HIV infection listing 14.08K for adults as proposed listing 14.11I;
- Remove current HIV infection listings 114.08A–K for children; and
- Add HIV infection listings 114.11A–H for children.

How did we develop these proposed rules?

In addition to our adjudicative experience and our review of the advances in medical knowledge, treatment, and methods of evaluating HIV infection, we asked experts and the public to provide us with information that helped us develop the proposals.

We published an Advanced Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** on March 18, 2008.[3] We informed the public that we were considering whether and how to update and revise the rules we use to evaluate HIV infection. We also invited interested persons and organizations to send us comments and suggestions about whether we should add, change, or remove any of the criteria in listings 14.08 and 114.08, and if so, what revisions did the commenters think we should make. We received comments from medical experts, advocates, and our adjudicators.[4]

In addition, we hosted a policy conference called ''HIV Infection in the Disability Programs'' in New York, N.Y., on September 10, 2008.[5] At this conference, we received comments and suggestions about how to update and revise our rules from professionals who work with patients with HIV infection, including physicians, medical experts, and advocates, as well as a person with HIV infection, and a mother of a child with HIV infection.

In 2009, we commissioned a report from the Institute of Medicine (IOM) of *The National Academies* on the criteria that we use to evaluate disability in persons with HIV infection. The IOM published the report, *HIV and Disability: Updating the Social Security*

[1] 58 FR 36008.

[2] 73 FR 14570.

[3] 73 FR 14409.

[4] We received seven comment letters. You may read the comment letters at *http://www.regulations.gov* under the same docket number as this notice.

[5] You can read a transcript of the policy conference at *http://www.ssa.gov/disability/SSA_HIV_Policy_Conf_Transcript.pdf*.

Listings, in 2010.[6] The report recommended ways to improve the utility of the HIV infection listings by improving the sensitivity and specificity of listing criteria to identify people with HIV infection who meet our definition of disability. The IOM committee reviewed the most current medical literature to determine the:

- Latest standards of care for HIV infection;
- Latest technology for the understanding of disease processes; and
- Latest science demonstrating the impact of HIV infection on patients' health and functional capacity.

Although we are not summarizing or formally responding to the comments that we received on the ANPRM or at our September 2008 policy conference, some of the changes we propose here reflect those comments.

Would our proposal to revise the listing for evaluating HIV infection affect people who are already receiving benefits based on HIV infection?

If these rules become final, we will not terminate any person's disability benefits solely because we have revised the listing for evaluating HIV infection, nor will we review prior allowances based on the HIV infection listing under the new rules. Unless we are otherwise required to do so (for example, by statute), we do not readjudicate previously decided cases when we revise our listings. We must periodically conduct continuing disability reviews to determine whether beneficiaries are still disabled.[7] When we do, we will not find that a person's disability has ended based on a change in a listing. In most cases, we must show that the person's impairment(s) has medically improved and that any medical improvement is ''related to the ability to work.''[8] Even where the impairment(s) has medically improved, our regulations provide that the improvement is not ''related to the ability to work'' if it continues to meet or medically equal the ''same listing section used to make our most recent favorable decision.'' This is true even if we have deleted the listing section we used to make the most recent favorable decision.[9] When we find that medical improvement is not related to the ability to work (or, in the case of a person under age 18, the impairment still meets or medically equals the prior listing), we will find that disability continues, unless an exception to medical improvement applies.

What changes are we proposing to the introductory text of the immune system disorders listings for adults?

We have made one editorial change to shorten the heading in proposed 14.00F by using the commonly known abbreviation for human immunodeficiency virus, HIV.

The following is a detailed explanation of the proposed changes to the introductory text.

Proposed Section 14.00A—What disorders do we evaluate under the immune system disorders listings?

We propose to revise current section 14.00A4 to explain that people with HIV infection have an increased susceptibility to ''common infections'' as well as to the conditions that we describe in our HIV infection listings. We also propose to revise this section to reflect our proposal to redesignate current listing 14.08 as proposed listing 14.11.

Proposed Section 14.00F—How do we document and evaluate HIV infection?

We propose to update and expand the information on HIV infection that is in current section 14.00F. We also propose to remove information that is obsolete or no longer useful to our adjudicators.

We propose to revise the sentence in the introductory language of current section 14.00F to reflect the redesignation of current listing 14.08 as proposed listing 14.11.

We propose to revise current section 14.00F1 by requiring positive findings on one or more definitive laboratory tests to document HIV infection in proposed section 14.00F1a. We would no longer accept nondefinitive tests as documentation of HIV infection as the guidance in current section 14.00F1b provides. We base the guidance in the current section on the prevailing state of medical knowledge and clinical practice at the time that we published final rules in 1993. The change that we are proposing in section 14.00F1a is consistent with the current prevailing state of medical knowledge and clinical practice that requires positive findings on a definitive laboratory test(s) to diagnose HIV infection.[10]

We propose to update the information on definitive laboratory tests in current section 14.00F1a that we use to document HIV infection as follows:

- Replace the ELISA screening test in current section 14.00F1a(i) with the more inclusive and commonly used term of enzyme immunoassay (EIA) in proposed section 14.00F1a(i);
- Combine positive ''viral load'' tests in current section 14.00F1a(ii) and HIV DNA detection by polymerase chain reaction (PCR) in current section 14.00F1a(iii) under the more commonly used term of HIV nucleic acid (DNA or RNA) detection test in proposed section 14.00F1a(ii);
- Replace the descriptive language of an HIV antigen test in current section 14.00F1a(iv) with the specific term of HIV p24 antigen test in proposed section 14.00F1a(iii);
- Replace the terminology in current section 14.00F1a(v) with simpler terminology in proposed section 14.00F1a(iv) regarding HIV in viral culture; and
- Redesignate current section 14.00F1a(vi) for ''[o]ther tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge'' as proposed section 14.00F1a(v).

We propose to remove the guidance on other acceptable documentation of HIV infection in current section 14.00F1b since we would no longer accept nondefinitive laboratory tests or methods to document HIV infection. We propose to move the guidance in current section 14.00F1—that we will make every reasonable effort to obtain the results of laboratory testing—to proposed section 14.00F1b. We also explain in this section that we would not purchase laboratory testing to establish whether you have HIV infection.

We propose to add guidance in section 14.00F1c to explain what documentation we require to document a diagnosis of HIV infection when we do not have a copy of a definitive laboratory test(s).

We propose to remove the information on CD4 tests in current section 14.00F2 because it contains general information that our adjudicators do not need, is inconsistent with our proposed requirement to document HIV infection by definitive laboratory test(s), and does not reflect the CD4 count or CD4 percentage criteria in proposed listings 14.11F and 14.11G. We explain how we would use CD4 measurements in the proposed

[6] You can read the report at *http://www.nap.edu/catalog.php?record_id=12941# toc.* You can also access the report at *http://www.ssa.gov/disabilityresearch/research.htm# HIV.*

[7] §§ 404.1589 and 416.989.

[8] §§ 404.1594 and 416.994.

[9] §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). Our regulations contain a similar provision for continuing disability reviews for children eligible for SSI based on disability. See, § 416.994a(b)(2).

[10] Centers for Disease Control and Prevention. Revised surveillance case definitions for HIV infection among adults, adolescents, and children aged <18 months and for HIV infection and AIDS among children aged 18 months to <13 years — United States, 2008. *Morbidity and Mortality Weekly Report* 2008; 57(RR–10):1–8. (available at *http://www.cdc.gov/mmwr/PDF/rr/rr5710.pdf).*

listings in proposed sections 14.00F4 and 14.00F5.

We propose to redesignate and revise current section 14.00F3 as proposed section 14.00F2. For the same reason articulated in proposed section 14.00F1a for the documentation of HIV infection, we would require positive findings on definitive laboratory tests to document a manifestation of HIV infection in proposed section 14.00F2a. This change is consistent with the current prevailing state of medical knowledge and clinical practice that requires positive findings on a definitive laboratory test(s) to diagnose a manifestation of HIV infection.[11]

We propose to move the guidance in current section 14.00F3a, that we will make every reasonable effort to obtain the results of laboratory testing, to proposed section 14.00F2b. We also explain in this section that we would not purchase laboratory testing to establish whether you have a manifestation of HIV infection.

We propose to move and revise the guidance in current section 14.00F3a on how to document a manifestation of HIV infection when we do not have a copy of a definitive laboratory test(s) to proposed section 14.00F2c.

We also propose to remove the guidance on other acceptable documentation of manifestations of HIV infection in current section 14.00F3b since we would no longer accept nondefinitive laboratory tests to document manifestations of HIV infection. We also propose to remove for the same reason the guidance for other acceptable documentation in current section 14.00F3b(i) for *Pneumocystis* pneumonia, current section 14.00F3b(ii) for *Cytomegalovirus,* current section 14.00F3b(iii) for toxoplasmosis of the brain, and current section 14.00F3b(iv) for candidiasis of the esophagus.

We propose to add information in proposed section 14.00F3 about disorders connected with HIV infection that reflects proposed new listings 14.11A for multicentric Castleman disease, 14.11B for primary central nervous system lymphoma, 14.11C for primary effusion lymphoma, 14.11D for progressive multifocal leukoencephalopathy, and 14.11E for pulmonary Kaposi sarcoma.

We provide information on multicentric Castleman disease (MCD) in proposed section 14.00F3a. We explain what distinguishes MCD from localized (or unicentric) Castleman disease. We also explain what we would require to establish the diagnosis of MCD.

We provide information on primary central nervous system lymphoma (PCNSL) in proposed section 14.00F3b. We explain where it originates and what we would require to establish the diagnosis of PCNSL.

We provide information on primary effusion lymphoma (PEL) in proposed section 14.00F3c. We explain what we would require to establish the diagnosis of PEL.

We provide information on progressive multifocal leukoencephalopathy (PML) in proposed section 14.00F3d. We identify clinical findings associated with PML. We also explain what we would require to establish the diagnosis of PML.

We provide information on pulmonary Kaposi sarcoma (PKS) in proposed section 14.00F3e. We explain how this form of Kaposi sarcoma differs from other forms of the condition and what we would require to establish the diagnosis of PKS.

We propose to remove the guidance on HIV infection manifestations specific to women in current section 14.00F4 for two reasons. First, the proposed HIV infection listings do not contain criteria that are gender-specific. We would evaluate the manifestations of HIV infection using the same criteria regardless of a person's gender. Second, while we recognize that manifestations of HIV infection may still affect a person's ability to function, we believe that the guidance in the following sections instruct our adjudicators to consider signs, symptoms, and effects of treatment when evaluating the severity of a person's HIV infection and resulting functional limitations.

- Current section 14.00G5, *How we evaluate the effects of treatment for HIV infection on your ability to function.*
- Current section 14.00H, *How do we consider your symptoms, including your pain, severe fatigue, and malaise?*

We would add information in proposed section 14.00F4 that reflects proposed new listing 14.11F. We explain that we would need one measurement of the absolute CD4 count to evaluate HIV infection under the proposed listing. We explain that we would require the absolute CD4 count to occur within the period we are considering in connection with an application or continuing disability review. We also explain that if there were more than one measurement of the absolute CD4 count within this period, we would use the lowest one to evaluate HIV infection under the proposed listing.

We propose to remove the guidance in current section 14.00F5 that explains how we evaluate involuntary weight loss for the purposes of current listing 14.08H for HIV wasting syndrome. We propose to remove this listing based on recommendations from the IOM report; therefore, we would no longer need the guidance in current section 14.00F5. Our adjudicators, however, would continue to consider involuntary weight loss resulting from HIV infection under our listing for repeated manifestations of HIV infection (proposed listing 14.11I, which is redesignated from current listing 14.08K). We also propose to remove the guidance in this section, which explains that we can evaluate HIV infection affecting the digestive system under current listing 5.08. It is redundant since we have similar guidance in current section 14.00J2e.

We would add information in proposed section 14.00F5 that reflects proposed new listing 14.11G. We explain how we would use a CD4 measurement (absolute count or percentage) and either a measurement of body mass index (BMI) or hemoglobin to evaluate HIV infection under the proposed listing. We also explain that we would require the measurements of CD4 (absolute count or percentage) and BMI or hemoglobin to occur within the period we are considering in connection with an application or continuing disability review. We also explain that if there is more than one measurement of CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we would use the lowest one to evaluate HIV infection under the proposed listing.

We propose to add information in new section 14.00F6 on how to evaluate complications of HIV infection requiring hospitalization under proposed listing 14.11H. We provide examples of complications that may result in hospitalization in proposed section 14.00F6a. We explain in proposed section 14.00F6b our requirements for evaluating hospitalizations under the proposed listing.

We propose to add information in new section 14.00F7 describing HIV-associated dementia (HAD). We explain that we evaluate HAD under current listing 12.02.

Section 14.00I—How do we use the functional criteria in these listings?

We propose to revise current section 14.00I by making a minor change to reflect the redesignation of current listing 14.08K as proposed listing 14.11I and clarifying what we mean by ''marked'' in proposed section 14.00I5.

We would remove the description of ''marked'' as ''more than moderate but less than extreme'' and replace it with an explanation based on the language

[11] *Id.*

describing the rating scale for mental disorders in current §§ 404.1520a(c)(4) and 416.920a(c)(4). This rating scale describes ''marked'' as the fourth point on a five-point rating scale. We explain that we would not require our adjudicators to use such a scale, but that ''marked'' would be the fourth point on a scale of ''no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation.'' With this guideline, it would be unnecessary to state that ''marked'' falls between ''moderate'' and ''extreme.''

What changes are we proposing to the immune system disorders listings for adults?

We propose to make the following changes to the HIV infection listing for adults:

- Remove current listings 14.08A–J;
- Add proposed listings 14.11A–H; and
- Redesignate and revise current listing 14.08K as proposed listing 14.11I.

We are proposing to remove current listings 14.08A–J based on our program experience, advances in medical knowledge, and recommendations from the IOM report. They are substantially the same listings that we published in 1993 and, as a result of advances in the treatment of HIV infection, some of the current listings no longer describe impairments that are of listing-level severity. This includes current HIV infection listings 14.08A, 14.08B, 14.08C, 14.08D, 14.08F, and 14.08J that the IOM report recommended we remove from the listings.

The IOM report recommended that we evaluate malignant neoplastic diseases associated with HIV infection, other than primary central nervous system lymphoma, primary effusion lymphoma, and pulmonary Kaposi sarcoma, under the malignant neoplastic diseases listings in 13.00. We, therefore, propose to remove current listing 14.008E for evaluating malignant neoplasms associated with HIV infection and to add proposed listings 14.11B for primary central nervous system lymphoma, 14.11C for primary effusion lymphoma, and 14.11E for pulmonary Kaposi sarcoma. We also propose to revise our guidance in current section 13.00A to indicate how we evaluate malignant neoplastic diseases associated with HIV infection in proposed section 13.00A.

We propose to remove current listing 14.08G for evaluating HIV encephalopathy, also known as HAD, which we would evaluate under current listing 12.02. We also propose to add the revision ''neurocognitive limitation (including dementia not meeting the criteria in 12.02)'' in proposed listing 14.11I. We would add this revision to indicate that we may consider neurocognitive limitations associated with HIV infection that do not satisfy the criteria in current listing 12.02 under proposed listing 14.11I.

We propose to remove current listings 14.08H for HIV wasting syndrome and 14.08I for diarrhea for the same reason. As noted in the IOM report, it is uncommon that these manifestations alone are predictive of disability, but they may be persistent and result in a marked level of limitation(s) in activities of daily living, maintaining social functioning, or completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace. We consider these areas of functioning under current listing 14.08K that we propose to redesignate as listing 14.11I. We therefore propose to remove current listings 14.08H and 14.08I and evaluate these manifestations under proposed listing 14.11I.

We describe proposed HIV infection listings 14.11A–I for adults below.

Listings 14.11A–E

We propose to add listings for the following HIV-associated disorders:

- Multicentric Castleman disease (14.11A);
- Primary central nervous system lymphoma (14.11B);
- Primary effusion lymphoma (14.11C);
- Progressive multifocal leukoencephalopathy (14.11D); and
- Pulmonary Kaposi sarcoma (14.11E).

Even with the advances in HIV treatment, there are people with HIV infection who continue to develop very aggressive and generally untreatable conditions. We propose, therefore, to add listings 14.11A–E for these conditions due to their aggressive nature and lack of response to treatment that result in loss of function consistent with a listing-level impairment when associated with HIV infection.

In addition to the proposed listings, we added these disorders to our list of Compassionate Allowances (CAL) conditions. CAL are a way of quickly identifying diseases and other medical conditions that invariably qualify under the Listings of Impairments based on minimal objective medical information. For more information about CAL, please visit our Web site at *http://www.ssa.gov/compassionateallowances/.*

Listing 14.11F, Absolute CD4 Count of 50 Cells/mm³ or Less

We propose to add listing 14.11F for absolute CD4 count of 50 cells/mm³ or less because it is predictive of disease progression, morbidity, and mortality that is consistent with a listing-level impairment when associated with HIV infection. We would require one absolute CD4 count of 50 cells/mm³ or less to satisfy this listing.

Listing 14.11G, Absolute CD4 Count of Less Than 200 Cells/mm³, or CD4 Percentage of Less Than 14 Percent

We propose to add listing 14.11G with criteria for specific combinations of values (either absolute CD4 count or CD4 percentage, and either BMI or hemoglobin measurement) because either of these combinations of values is indicative of a loss of function that is consistent with a listing-level impairment when associated with HIV infection. We would require only one set of values at the specified listing-level to satisfy this listing.

Listing 14.11H, Complication(s) of HIV Infection Requiring at Least Three Hospitalizations

We propose to add listing 14.11H to provide criteria that recognize the medical severity of complications of HIV infection that lead to at least three hospitalizations in a 12-month period. Each hospitalization would need to last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization, with at least 30 days between hospitalizations. We would require that each hospitalization last at least 48 hours because we believe this period is indicative of a severe complication of HIV infection. We would include the hours the person spends in the emergency department immediately before hospital admission because the person is likely to be receiving the same intensity of care as he or she will receive in the hospital.

Listing 14.11I, Repeated Manifestations of HIV Infection

We propose to redesignate and revise current listing 14.08K as proposed listing 14.11I. We would revise the listing to reflect the changes that we have made in proposed listings 14.11A–H. We would also expand our guidance on manifestations we evaluate under the listing by adding ''distal sensory polyneuropathy,'' ''infections (bacterial, fungal, parasitic, or viral),'' ''lipodystrophy (lipoatrophy or lipohypertrophy),'' and ''osteoporosis'' as new examples based on recommendations from the IOM report

and our program experience. In addition, we would revise ''cognitive or other mental limitation'' used in current listing 14.08K to ''neurocognitive limitation (including dementia not meeting the criteria in 12.02).'' We would do this because it is a better description of the limitation associated with HIV infection and to indicate that we may consider neurocognitive limitations associated with HIV infection that do not satisfy the criteria in current listing 12.02 under proposed listing 14.11I.

What changes are we proposing to the introductory text of the immune system disorders listings for children?

The same basic rules for evaluating immune system disorders in adults also apply to children. Except for minor editorial changes to make the text specific to children, we have repeated much of the introductory text of proposed section 14.00 in the introductory text of proposed section 114.00. Since we have already described these proposed rules under the explanation of proposed section 14.00, we describe here only the significant sections of the proposed rules that are unique to children or that require further explanation.

In proposed section 114.00F1a(iii), we clarify that the HIV p24 antigen test is a definitive laboratory test for documentation of HIV infection for any child age 1 month or older.

We propose to remove current section 114.00F1a(vi) because the immunoglobulin serological assay that we list in this section is no longer used to document HIV infection.

We propose to remove current section 114.00F1b because the laboratory tests and findings described in this section no longer represent the current standard of medical practice for documenting HIV infection and have been supplanted by the laboratory tests listed in proposed section 114.00F1a.

In proposed section 114.00F4, we explain that we will require one measurement of an absolute CD4 count for children from age 5 to attainment of age 18, or CD4 percentage for children from birth to attainment of age 5, to evaluate HIV infection under proposed listing 114.11F.

We propose to add section 114.00F5. We explain we would evaluate linear growth failure under the growth impairment listing in 100.00. We also explain that if a child's growth failure does not meet or medically equal a listing in 100.00, we will consider whether the child's HIV infection meets or medically equals the criteria of a listing in another body system. We provide an example of when we would evaluate a child's HIV infection under the digestive system listing in 105.00.

We propose to move and revise the guidance in current section 114.00F4 to proposed section 114.00F7. We would remove the examples of onset and HIV manifestations at different ages in current section 114.00F4a. This information was useful when we first published the HIV infection listings in 1993. Our adjudicators, however, no longer need this information based on our extensive program experience evaluating HIV infection under our listings. We would revise the information about neurological and growth abnormalities under proposed sections 114.00F5 and 114.00F7.

We propose to redesignate and revise current section 114.00F4b as proposed section 114.00F7. We would primarily retain the information in the current section with editorial changes for clarity. We would explain, however, that the loss of acquired developmental milestones in infants and young children is also known as developmental regression. We would also explain that we evaluate developmental delays without regression under 111.00.

We would remove current section 114.00F4c because it provides information on evaluating bacterial infections under current listing 114.08A4 and pelvic inflammatory disease under current listing 114.08A5. We would no longer need this information because we are proposing to remove both of the listings.

What changes are we proposing to the immune system disorders listings for children?

The following is a description of the significant proposed changes to the immune system disorders listings for children when they are different from the changes we propose for adults or require additional explanation.

We propose to remove current listing 114.08H for evaluating growth disturbance with an involuntary weight loss (or failure to gain weight at an appropriate rate for age) that meets specified criteria. We would remove this listing because, as we explain in proposed section 114.00F5, we would evaluate this impairment under a growth impairment listing in 100.00 or a digestive system listing in 105.00.

We propose to remove current listing 114.08J for evaluating lymphoid interstitial pneumonia/pulmonary lymphoid hyperplasia (LIP/PLH complex). We propose to remove this listing based on the recommendation in the IOM report that LIP/PLH complex no longer describes an impairment of listing-level severity.

Listing 114.11F, Absolute CD4 Count or CD4 Percentage

Proposed listing 114.11F for children is similar to proposed listing 14.11F for adults, except for the CD4 percentage requirement for children from birth to the attainment of age 5. We would require a CD4 percentage in proposed listing 114.11F1 since it fluctuates less than absolute CD4 counts for children prior to the attainment of age 5 and is a more consistent and reliable measurement of immune suppression. We would require the same absolute CD4 count of 50 cells/mm^3 or less for children age 5 to the attainment of age 18 in proposed listing 114.11F2 as for adults in proposed 14.11F because children in that age range have CD4 counts comparable to those levels found in adults.

Listing 114.11H, A Neurological Manifestation of HIV Infection

We propose to redesignate and revise current listing 114.08G as proposed listing 114.11H. In proposed listing 114.11H1, we would remove ''marked delay in achieving'' developmental milestones because we evaluate infants and young children with serious developmental delays without regression under 111.00. We would also add ''documented on two examinations at least 60 days apart'' to the loss of previously acquired developmental milestones or intellectual ability (including the sudden onset of a new learning disability) in proposed listing 114.11H1. This chronicity supports the severity of a listing-level impairment.

We propose to redesignate and revise current listing 114.08G3 as proposed listing 114.11H2. We would add ''documented on two examinations at least 60 days apart'' for the same reason as in proposed listing 114.11H1.

We propose to redesignate and revise current listing 114.08G2 as proposed listing 114.11H3 for microcephaly and H4 for brain atrophy. In proposed listing 114.11H3, we change ''acquired microcephaly'' used in current listing 114.08G2 to ''microcephaly'' because ''acquired'' is unnecessary. We would evaluate any finding of microcephaly associated with HIV infection under this listing for children. We also specify the percentile of head circumference that would establish listing-level severity and add the same requirement of ''documented on two examinations at least 60 days apart'' as in the proposed listings 114.11H1 and H2 for the same reason.

In proposed listing 114.11H4, we clarify that we document brain atrophy by appropriate medically acceptable imaging.

Why are we not proposing a listing with functional criteria for children with HIV infection?

On August 19, 2010, we published a Notice of Proposed Rulemaking (NPRM) for evaluating mental disorders.[12] We proposed in the NPRM to remove each of the current listings in 114.00 of the immune system disorders that cross-refer to the functional criteria in current listings 112.02 and 112.12. We proposed to remove these listings without replacement, including current listing 114.08L for HIV infection.

Under current listing 114.08L, we use the functional criteria in the childhood mental disorders listings to evaluate both physical and mental limitations that result from HIV infection. Due to the changes that we are proposing in the mental disorders listing, it would no longer be appropriate to cross-refer to the criteria in them. Moreover, we may find children disabled under the Supplemental Security Income program based on functional equivalence to the listings. Functional equivalence considers their functional limitations in domains that we designed to cover all childhood physical and mental functioning.

We are not proposing a similar change to current adult listing 14.08K because it contains specific criteria for evaluating functioning without cross-referring to the mental disorders listings. We are still considering the comments that we received in response to the NPRM for evaluating mental disorders and we will address them in the final rules.

Other Changes

We also propose conforming changes to current sections 5.00D4a(i), 5.00D4b(i) and (ii), 105.00D4a(i), and 105.00D4b(i) and (ii) of the digestive disorders listings. We would revise these sections to clarify how comorbid disorders may affect the clinical course of viral hepatitis infection(s) and to provide information on diagnostic tests and treatments for chronic hepatitis B infections.

We also propose to revise current sections 8.00D3 and 108.00D3 of the skin disorders listings to indicate that we evaluate HIV infection under proposed listings 14.11 and 114.11.

Finally, we propose to revise current sections 13.00A and 113.00A of the malignant neoplastic diseases listings. We would revise these sections to indicate that we evaluate primary central nervous system lymphoma, primary effusion lymphoma, and pulmonary Kaposi sarcoma associated with HIV infection under proposed listings 14.11B, C, or E and 114.11B, C, or E. We also propose to evaluate all other malignant neoplasms associated with HIV infection under the current listings for the malignant neoplastic diseases body system or under proposed listings 14.11F–I and 114.11F–H of the immune system disorders body system.

What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them.[13]

How long would these rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand, e.g., grouping and order of sections, use of headings, paragraphing?

When will we start to use these rules?

We will not use these rules until we evaluate public comments and publish final rules in the **Federal Register**. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of those relevant comments we received along with responses and an explanation of how we will apply the new rules.

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We have consulted with the Office of Management and Budget (OMB) and determined that this NPRM meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563, and was subject to OMB review.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

These proposed rules do not create any new or affect any existing collections, and therefore, do not require OMB approval under the Paperwork Reduction Act.

References

We consulted the following references when we developed these proposed rules. Some of the references include a DOI name. You can access a reference with a DOI name by typing the DOI name in the DOI finder at *http://dx.doi.org.*

Bartlett, John G., Joel E. Gallant, and Paul A. Pham. (2009). *Medical Management of HIV Infection.* Durham, NC: Knowledge Source Solutions, LLC.

Belperio, P. S., & Rhew, D. C. (2004). Prevalence and outcomes of anemia in individuals. *The American Journal of Medicine,* 116, 27S–43S. doi:10.1016/j.amjmed.2003.12.010.

Berger, J. (2010). Progressive multifocal encephalopathy. In D. Schlossberg (Ed.), *Current Therapy of Infectious Disease* (pp. 1–6). Philadelphia, PA: W.B. Saunders, Harcourt Health Sciences. (Original work published 2002).

Boyd, K., Dunn, D., & Castro, H., et al. (2010). Discordance between CD4 cell count and CD4 cell percentage: Implications for when to start antiretroviral therapy in HIV–1 infected children. *AIDS,* 24(8), 1213–1217.

Branson, B. M., Handsfield, H. H., Lampe, M. A., Janssen, R. S., Taylor, A. W., Lyss, S. B., et al. (2006). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *Morbidity and Mortality Weekly Report* 2006; 55(RR–14):1–17. (Retrieved from: *http://www.cdc.gov/mmwr/PDF/rr/rr5514.pdf*).

[12] 75 FR 51336.

[13] 42 U.S.C. 405(a), 902(a)(5), and 1383(d)(1).

Calis, C., et al. (2008). HIV-associated anemia in children: a systematic review from a global perspective. *AIDS,* 22(10), 1099–1112. doi:10.1097/QAD.0b013e3282fa759f.

Callens, F., Shabani, N., Lusiama, J., Lelo, P., Kitetlel, F., Colebunders, R., Gizlice, Z., Edmonds, A., Van Rie, A. & Behets, F. (2009). Mortality and associated factors after initiation of pediatric antiretroviral treatment in the Democratic Republic of the Congo. *The Pediatric Infectious Disease Journal,* 28(1), 35–40.

Campsmith, M. L., Rhodes, P. H., Hall, I., & Green, T. A. (2009). Undiagnosed HIV prevalence among adults and adolescents in the United States at the end of 2006. *Journal of Acquired Immune Deficiency Syndromes,* 00(0), 1–6. Retrieved from: *http://journals.lww.com/jaids/Fulltext/2010/04150/Undiagnosed_HIV_Prevalence_Among_Adults_and.9.aspx.*

Centers for Disease Control. Revision of the CDC surveillance case definition for acquired immunodeficiency syndrome. *Morbidity and Mortality Weekly Report* 1987; 36(1S):1–15. Retrieved from: *http://www.cdc.gov/mmwr/pdf/other/mmsu3601.pdf.*

Centers for Disease Control and Prevention. Appendix: Revised surveillance case definition for HIV infection. *Morbidity and Mortality Weekly Report* 1999; 48(RR–13): 29–31. Retrieved from: *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm.*

Centers for Disease Control and Prevention. Revised surveillance case definitions for HIV infection among adults, adolescents, and children aged <18 months and for HIV infection and AIDS among children aged 18 months to <13 years—United States, 2008. *Morbidity and Mortality Weekly Report* 2008; 57(RR–10):1–8. Retrieved from *http://www.cdc.gov/mmwr/PDF/rr/rr5710.pdf.*

Centers for Disease Control and Prevention. Guidelines for the prevention and treatment of opportunistic infections among HIV-exposed and HIV-infected children: Recommendations from CDC, the National Institutes of Health, the HIV Medicine Association of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Academy of Pediatrics. *Morbidity and Mortality Weekly Report* 2009; 58(RR–11):1–176. Retrieved from: *http://www.cdc.gov/mmwr/pdf/rr/rr5811.pdf.*

Chen, Y., Rahemtullah, A., & Hochberg, E. (2007). Primary effusion lymphoma. *The Oncologist,* 12(5), 569–576. doi:10.1634/theoncologist.12–5–569.

Collins, I., Jourdain, G., Hansudewechakul, R., Kanjanavanit, S., Hongsiriwon, S., Ngampiyasakul, C., Duong, T., Le Coeur, S., Jaffar, S. & Lallemant, M. (2010). Long-term survival of HIV-infected children receiving antiretroviral therapy in Thailand: A 5-year observational cohort study. *Clinical Infectious Diseases,* 51(12), 1449–1457. doi:10.1086/657401.

Corcoran, C., & Grinspoon, S. (1999). Treatments for wasting in patients with the acquired immune deficiency syndrome. *The New England Journal of Medicine,* 340 (22), 1740–1750. doi:10.1056/NEJM199906033402207.

Denny, T., Yogev, R., Gelman, R. et al. (1992). Lymphocyte subsets in healthy children during the first 5 years of life. *JAMA,* 267(11), 1484–1488. doi:10.1001/jama.1992.03480110060034.

Dunn, D., Woodburn, P., Duong, T., Peto, J., Phillips, A., Gibb, D., & Porter, K. (2008). Current CD4 cell count and the short-term risk of AIDS and death before the availability of effective antiretroviral therapy in HIV-infected children and adults. *The Journal of Infectious Diseases,* 197(3), 398–404. doi:10.1086/524686.

European Collaborative Study. (2005). Age-related standards for total lymphocyte, CD4 and CD8 T-cell counts in children born in Europe. *The Pediatric Infectious Disease Journal,* 24(7), 595–600.

HIV Paediatric Prognostic Markers Collaborative Study Group. (2003). Short-term risk of disease progression in HIV–1-infected children receiving no antiretroviral therapy or zidovudine monotherapy: A meta-analysis. *The Lancet,* 362(9396), 1605–1611. doi:10.1016/S0140–6736(03)14793–9.

Human Immunodeficiency Virus (HIV) Infection in Children. (2007). In *Merck Manual Home Health Handbook.* Retrieved from: *http://www.merckmanuals.com/home/print/sec23/ch273/ch273e.html.*

Institute of Medicine. (2010). *HIV and Disability: Updating the Social Security Listings.* Washington, DC: The National Academies Press. Retrieved from: *http://www.nap.edu/catalog.php?record_id=12941#toc.*

Justice, A., Gange, S., Tate, J., Jacobson, L., Gebo, K., Althoff, K., . . . Moore, R. (2010). Report to the Institute of Medicine committee evaluating disability criteria for those with HIV infection. *HIV and Disability: Updating the Social Security Listings,* Institute of Medicine, Washington, DC: The National Academies Press.

Justice, A., McGinnis, K., Braithwaite, R., May, M., Covinsky, K., Roberts, M., et al. (2010). Towards a combined prognostic index for survival in HIV infection: The role of 'non-HIV' biomarkers. *HIV Medicine,* 11(2), 143–151. Retrieved from: *http://www.medscape.com/viewarticle/715224.*

Kaplan, J. E., Benson, C., & Masur, H., et al. (2009). Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. *Morbidity and Mortality Weekly Report,* 58 (RR04), 1–198. Retrieved from: *http://www.cdc.gov/mmwr/pdf/rr/rr5804.pdf*).

Kapogiannis, B., Soe, M., & Nesheim, S. et al. (2008). Trends in bacteremia in the pre- and post-highly active antiretroviral therapy era among HIV-infected children in the U.S. Perinatal AIDS Collaborative Transmission Study (1986–2004). *Pediatrics,* 121(5), e1229–e1239. doi:10.1542/peds.2007–0871.

Kaposi Sarcoma. (n.d.). *What Is Kaposi Sarcoma?* Retrieved from: *www.cancer.org/Cancer/KaposiSarcoma/DetailedGuide/kaposi-sarcoma-what-is-kaposi-sarcoma.*

Kimmel, A. D., Goldie, S. J., Walensky, R. P., Losina, E., Weinstein, M. C., Paltiel, A. D., . . . Freedberg, K. (2005). Optimal frequency of CD4 cell count and HIV RNA monitoring prior to initiation of antiretroviral therapy in HIV-infected patients. *Antiviral Therapy,* 10(1), 41–52. Retrieved from: *http://www.intmedpress.com/serveFile.cfm?sUID=1a6a19e0-feb5–47c4-bbc5-aa87ffd4035b.*

Lodi, S., Guiguet, M., Costagliola, D., Fisher, M., Luca, A. d., & Porter, K. (2010). Kaposi sarcoma incidence and survival among HIV-infected homosexual men after HIV seroconversion. *Journal of the National Cancer Institute,* 102(11), 784–792. doi:10.1093/jnci/djq134.

Mandell, Bennett, & Dolin (2007). Clinical findings: acute retroviral syndrome. *Principles and Practice of Infectious Diseases, 6th ed.,* (pp. 1–26). Elsevier Inc. (Original work published 2005).

Mocroft, A., Ledergerber, B., Zilmer, K., Kirk, O., Hirschel, B., Viard, J. P., . . . Lundgren, J. D. (2007). Short-term clinical disease progression in HIV–1-positive patients taking combination antiretroviral therapy: the EuroSIDA risk-score. *AIDS,* 21(14), 1867–1875. Retrieved from: *http://www.medscape.com/viewarticle/562494.*

Mocroft, A., & Lundgren, J. D. (2009). Use of risk equations for predicting disease progression in HIV infection. *Clinical Infectious Diseases,* 2009(48), 951–953. doi:10.1086/597355.

Mylona, E., Baraboutis, I., Lekakis, L., Georgiou, O., Papastamopoulos, V., & Skoutelis, A. (2008). Multicentric Castleman's disease in HIV infection: A systematic review of the literature. *AIDS Reviews,* 10(1), 25–35. Retrieved from: *http://www.aidsreviews.com/files/2008_10_1_025–035.pdf.*

National Cancer Institute. (2010). AIDS-related lymphoma treatment. Retrieved from: *http://www.cancer.gov/cancertopics/pdq/treatment/AIDS-related-lymphoma/HealthProfessional.*

National Institutes of Health, National Institute of Neurological Disorders and Stroke (NINDS). (2011). *NINDS Neurological Complications of AIDS Information Page.* Retrieved from: *http://www.ninds.nih.gov/disorders/aids/aids.htm.*

Oliveira, R., Krauss, M., Essama-Bibi, S. et al. (2010). Viral load predicts new World Health Organization stage 3 and 4 events in HIV-infected children receiving highly active antiretroviral therapy, independent of CD4 T lymphocyte value. *Clinical Infectious Diseases,* 51(11), 1325–1333. doi:10.1086/657119.

Papatheodoridis, G., & Hadziyannis, S. (2004). Review article: Current management of chronic hepatitis B.

Alimentary Pharmacology and Therapeutics, 19(1), 25–37. doi:10.1046/j.1365–2036.2003.01810.x.

Poonam, S., Varman, M., Kourtis, A., & Sharma, S. (2011). *Pediatric Hepatitis B Treatment & Management.* Retrieved from: *http://emedicine.medscape.com/article/964662-treatment.*

Ramachandran, T. S. (2011). *Primary CNS Lymphoma.* Retrieved from: *http://emedicine.medscape.com/article/1157638.*

Read, Jennifer S. (2007). Diagnosis of HIV–1 infection in children younger than 18 months in the United States. *Pediatrics,* 120(6), e1547–62. doi:101542/peds.2007–2951.

Sarrot-Reynauld, F. (2001). Castleman's disease. In *Orphanet Encyclopedia.* Retrieved from: *http://www.orpha.net/data/patho/GB/uk-castleman.pdf.*

Simonelli, C., Spina, M., Cinnelli, R., Talamini, R., Tedeschi, R., Gloghini, A., . . . Tirelli, U. (2003). Clinical features and outcome of primary effusion lymphoma in HIV-infected patients: A single-institution study. *Journal of Clinical Oncology,* 21(21), 3948–3954. doi:10.1200/JCO.2003.06.013.

Singh, N. N, Sahai-Srivastava, S., Varpetian, A., et al. (2011). *HIV Encephalopathy and AIDS Dementia Complex.* Retrieved from: *http://emedicine.medscape.com/article/1166894.*

Singh, N. N., & Thomas, F. P. (2011). *Progressive Multifocal Leukoencephalopathy in HIV.* Retrieved from: *http://emedicine.medscape.com/article/1167145.*

Srasuebkul, Preeyaporn, Poh Lian Lim, Jeffery Smith, Matthew G. Law, et al. (2009). Short-term clinical disease progression in HIV-infected patients receiving combination antiretroviral therapy: Results from the TREAT Asia HIV Observational Database. *Clinical Infectious Diseases,* 2009(48), 940–950. doi:10.1086/597354.

Sullivan, R., Pantanowitz, L., Casper, C., Stebbing, J., & Dezube, B. (2008). Epidemiology, pathophysiology and treatment of Kaposi sarcoma-associated herpesvirus disease: Kaposi sarcoma, primary effusion lymphoma, and multicentric Castleman disease. *Clinical Infectious Diseases,* 47(9), 1209–1215. doi:10.1086/592298.

World Health Organization Library. (2007). WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children. *World Health Organization,* 1–40.

Zhao, Y., Encinosa, W. and Hellinger, F. *HIV Hospitalizations in 1998 and 2005.* HCUP Statistical Brief # 41. November 2007. Agency for Healthcare Research and Quality, Rockville, MD. Retrieved from:*http://www.hcup-us.ahrq.gov/reports/statbriefs/sb41.pdf.*

Zia, M., Taha, H. M., & Jabbar, A. A. (2009). *AIDS-Related Lymphomas.* Retrieved from: *http://emedicine.medscape.com/article/1389907.*

We included these references in the rulemaking record for these proposed rules and will make them available for inspection by interested individuals who make arrangements with the contact person identified above.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects in 20 CFR Part 404

Administrative practice and procedure; Blind, Disability benefits; Old-Age, Survivors, and Disability Insurance; Reporting and recordkeeping requirements; Social Security.

Dated: February 18, 2014.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend 20 CFR chapter III, part 404 subpart P as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—Determining Disability and Blindness

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 by:

■ a. Revising item 15 of the introductory text before part A;

■ b. Adding a sentence to paragraph 5.00D4a(i) of part A;

■ c. Revising paragraph 5.00D4b of part A;

■ d. Revising the last sentence of paragraph 8.00D3 of part A;

■ e. Revising paragraph 13.00A of part A;

■ f. Revising paragraphs 14.00A4, 14.00F, 14.00I1, and 14.00I5 of part A;

■ g. Removing and reserving paragraph 14.08 of part A;

■ h. Adding paragraph 14.11 to part A;

■ i. Adding a sentence to paragraph 105.00D4a(i) of part B;

■ j. Revising paragraph 105.00D4b of part B;

■ k. Revising the last sentence of paragraph 108.00D3 of part B;

■ l. Revising paragraph 113.00A of part B;

■ m. Revising paragraphs 114.00A4 and 114.00F of part B, and

■ n. Removing and reserving paragraph 114.08 of part B; and

■ o. Adding paragraph 114.11 to part B.

The revisions and additions read as follows:

APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

* * * * *

15. Immune System Disorders (14.00 and 114.00): [date 5 years from the effective date of the final rule].

* * * * *

Part A

* * * * *

5.00 DIGESTIVE SYSTEM

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D. *How do we evaluate chronic liver disease?*

* * * * *

4. *Chronic viral hepatitis infections.*

a. *General.*

(i) * * * Comorbid disorders, such as HIV infection, may accelerate the clinical course of viral hepatitis infection(s) or may result in a poorer response to medical treatment.

* * * * *

b. *Chronic hepatitis B virus (HBV) infection.*

(i) *Chronic HBV infection* can be diagnosed by the detection of hepatitis B surface antigen (HBsAg) or hepatitis B virus DNA (HBV DNA) in the blood for at least 6 months. In addition, detection of the hepatitis B e antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis, ESLD, and hepatocellular carcinoma. (HBeAg may also be referred to as ''hepatitis B early antigen'' or ''hepatitis B envelope antigen.'')

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis, ESLD, and hepatocellular carcinoma. Treatment usually includes interferon injections, oral antiviral agents, or a combination of both. Common adverse effects of treatment are the same as noted in 5.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

* * * * *

8.00 SKIN DISORDERS

* * * * *

D. *How do we assess impairments that may affect the skin and other body systems?*

* * * * *

3. * * * We evaluate SLE under 14.02, scleroderma under 14.04, Sjögren's syndrome under 14.10, and HIV infection under 14.11.

* * * * *

13.00 MALIGNANT NEOPLASTIC DISEASES

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in 14.11B to evaluate primary central nervous system lymphoma, 14.11C to evaluate primary effusion lymphoma, and 14.11E to evaluate pulmonary Kaposi

sarcoma if you also have HIV infection. We evaluate all other malignant neoplasms associated with HIV infection, for example, Hodgkin's lymphoma or non-pulmonary Kaposi sarcoma, under this body system or under 14.11F–I in the immune system disorders body system.

* * * * *

14.00 IMMUNE SYSTEM DISORDERS

A. *What disorders do we evaluate under the immune system disorders listings?*

* * * * *

4. *Human immunodeficiency virus (HIV) infection (14.00F).* HIV infection may be characterized by increased susceptibility to common infections as well as opportunistic infections, cancers, or other conditions listed in 14.11.

* * * * *

F. *How do we document and evaluate HIV infection?* Any individual with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 14.11 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.

1. *Documentation of HIV infection.*

a. We require positive findings on one or more of the following definitive laboratory tests:

(i) HIV antibody screening test (for example, enzyme immunoassay, or EIA), confirmed by a supplemental HIV antibody test such as the Western blot, an immunofluorescence assay, or an HIV–1/HIV–2 antibody differentiation immunoassay.

(ii) HIV nucleic acid (DNA or RNA) detection test (for example, polymerase chain reaction, or PCR).

(iii) HIV p24 antigen test.

(iv) Isolation of HIV in viral culture.

(v) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results.

2. *Documentation of the manifestations of HIV infection.*

a. We require positive findings of manifestations of HIV infection on culture, microscopic examination of biopsied tissue or other material (for example, bronchial washings), serologic tests, or on other generally acceptable definitive tests consistent with the prevailing state of medical knowledge and clinical practice.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have a manifestation of HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your manifestation of HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your manifestation of HIV infection and provide the results.

3. *Disorders associated with HIV infection (14.11A–E).*

a. *Multicentric Castleman disease* (MCD, 14.11A) affects multiple groups of lymph nodes and organs containing lymphoid tissue. This widespread involvement distinguishes MCD from *localized* (or unicentric) Castleman disease, which affects only a single set of lymph nodes. We require characteristic findings on microscopic examination of the biopsied lymph nodes to establish the diagnosis.

b. *Primary central nervous system lymphoma* (PCNSL, 14.11B) originates in the brain, spinal cord, meninges, or eye. Imaging tests (for example, MRI) of the brain, while not diagnostic, may show a single lesion or multiple lesions in the white matter of the brain. We require characteristic findings on microscopic examination of the cerebral spinal fluid or of the biopsied brain tissue to establish the diagnosis.

c. *Primary effusion lymphoma* (PEL, 14.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ to establish the diagnosis.

d. *Progressive multifocal leukoencephalopathy* (PML, 14.11D) is a progressive neurological degenerative syndrome caused by the JC virus in immunosuppressed people. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebral spinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus to establish the diagnosis.

e. *Pulmonary Kaposi sarcoma* (Kaposi sarcoma in the lung, 14.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, the gastrointestinal tract) have a more variable prognosis. We require characteristic findings on microscopic examination of the induced sputum or bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, to establish the diagnosis.

4. *CD4 measurement (14.11F).* To evaluate your HIV infection under 14.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count). This measurement must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your absolute CD4 count within this period, we will use your lowest absolute CD4 count.

5. *Measurement of CD4 and either body mass index or hemoglobin (14.11G).* To evaluate your HIV infection under 14.11G, we require one measurement of your absolute CD4 count or CD4 percentage *and* either a measurement of your body mass index (BMI) or hemoglobin. These measurements must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we will use the lowest of your CD4 (absolute count or percentage), BMI, or hemoglobin. We calculate your BMI using the formulas in 5.00G2.

6. *Complications of HIV infection requiring hospitalization (14.11H).*

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and *Pneumocystis* pneumonia and other severe infections.

b. Under 14.11H, we require three hospitalizations within a 12-month period resulting from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review.

7. *HIV-associated dementia (HAD).* HAD (also known as AIDS dementia complex, HIV dementia, or HIV encephalopathy) is an advanced neurocognitive disorder, characterized by a significant decline in cognitive functioning. We evaluate HAD under 12.02.

* * * * *

I. *How do we use the functional criteria in these listings?*

1. The following listings in this body system include standards for evaluating the functional limitations resulting from immune system disorders: 14.02B, for systemic lupus erythematosus; 14.03B, for systemic vasculitis; 14.04D, for systemic sclerosis (scleroderma); 14.05E, for polymyositis and dermatomyositis; 14.06B, for undifferentiated and mixed connective tissue disease; 14.07C, for immune deficiency disorders, excluding HIV infection; 14.09D, for inflammatory arthritis; 14.10B, for Sjögren's syndrome; and 14.11I, for HIV infection.

* * * * *

5. *Marked* limitation means that the symptoms and signs of your immune system disorder interfere *seriously* with your ability to function. Although we do not require the use of such a scale, ''marked'' would be the fourth point on a five-point scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. * * *

* * * * *

14.01 *Category of Impairments, Immune System Disorders.*

* * * * *

14.11 *Human immunodeficiency virus (HIV) infection.* With documentation as described in 14.00F1 and one of the following:

A. Multicentric Castleman disease (see 14.00F3a). OR

B. Primary central nervous system lymphoma (see 14.00F3b). OR

C. Primary effusion lymphoma (see 14.00F3c). OR

D. Progressive multifocal leukoencephalopathy (see 14.00F3d). OR

E. Pulmonary Kaposi sarcoma (see 14.00F3e). OR

F. Absolute CD4 count of 50 cells/mm^3 or less (see 14.00F4). OR

G. Absolute CD4 count of less than 200 cells/mm^3 or CD4 percentage of less than 14 percent (see 14.00F5), *and* one of the following:

1. BMI measurement of less than 18.5; or

2. Hemoglobin measurement of less than 8.0 grams per deciliter (g/dL). OR

H. Complication(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 14.00F6). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. OR

I. Repeated (as defined in 14.00I3) manifestations of HIV infection, including those listed in 14.11A–H, but without the requisite findings for those listings (for example, Kaposi sarcoma not meeting the criteria in 14.11E), or other manifestations (for example, diarrhea, distal sensory polyneuropathy, glucose intolerance, hepatitis, infections (bacterial, fungal, parasitic, or viral), lipodystrophy (lipoatrophy or lipohypertrophy), muscle weakness, myositis, neurocognitive limitation (including dementia not meeting the criteria in 12.02), oral hairy leukoplakia, osteoporosis, pancreatitis, peripheral neuropathy) resulting in significant, documented symptoms or signs (for example, fever, headaches, insomnia, involuntary weight loss, malaise, nausea, night sweats, pain, severe fatigue, or vomiting) and one of the following at the marked level:

1. Limitation of activities of daily living.

2. Limitation in maintaining social functioning.

3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

* * * * *

Part B

* * * * *

105.00 DIGESTIVE SYSTEM

* * * * *

D. *How do we evaluate chronic liver disease?*

* * * * *

4. *Chronic viral hepatitis infections.*

a. *General.*

(i) * * * Comorbid disorders, such as HIV infection, may accelerate the clinical course of viral hepatitis infection(s) or may result in a poorer response to medical treatment.

* * * * *

b. *Chronic hepatitis B virus (HBV) infection.*

(i) *Chronic HBV infection* can be diagnosed by the detection of hepatitis B surface antigen (HBsAg) or hepatitis B virus DNA (HBV DNA) in the blood for at least 6 months. In addition, detection of the hepatitis B e antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis, ESLD, and hepatocellular carcinoma. (HBeAg may also be referred to as ''hepatitis B early antigen'' or ''hepatitis B envelope antigen.'')

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis, ESLD, and hepatocellular carcinoma. Treatment usually includes interferon injections, oral antiviral agents, or a combination of both. Common adverse effects of treatment are the same as noted in 105.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

* * * * *

108.00 SKIN DISORDERS

* * * * *

D. *How do we assess impairments that may affect the skin and other body systems?*

* * *

* * * * *

3. * * * We evaluate SLE under 114.02, scleroderma under 114.04, Sjögren's syndrome under 114.10, and HIV infection under 114.11.

* * * * *

113.00 MALIGNANT NEOPLASTIC DISEASES

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. If you have HIV infection, we use the criteria in 114.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin. We use the criteria in 114.11B to evaluate primary central nervous system lymphoma, 114.11C to evaluate primary effusion lymphoma, and 114.11E to evaluate pulmonary Kaposi sarcoma if you also have HIV infection. We evaluate all other malignant neoplasms associated with HIV infection, for example, Hodgkin's lymphoma or non-pulmonary Kaposi sarcoma, under this body system or under 114.11F–I in the immune system disorders body system.

* * * * *

114.00 IMMUNE SYSTEM DISORDERS

A. *What disorders do we evaluate under the immune system disorders listings?*

* * * * *

4. *Human immunodeficiency virus (HIV) infection (114.00F).* HIV infection may be characterized by increased susceptibility to common infections as well as opportunistic infections, cancers, or other conditions listed in 114.11.

* * * * *

F. *How do we document and evaluate HIV infection?* Any child with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 114.11 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.

1. *Documentation of HIV infection.*

a. We require positive findings on one or more of the following definitive laboratory tests:

(i) HIV antibody screening test (for example, enzyme immunoassay, or EIA), confirmed by a supplemental HIV antibody test such as the Western blot or immunofluorescence assay, for any child age 18 months or older.

(ii) HIV nucleic acid (DNA or RNA) detection test (for example, polymerase chain reaction, or PCR).

(iii) HIV p24 antigen test, for any child age 1 month or older.

(iv) Isolation of HIV in viral culture.

(v) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results.

2. *Documentation of the manifestations of HIV infection.*

a. We require positive findings of manifestations of HIV infection on culture, microscopic examination of biopsied tissue or other material (for example, bronchial washings), serologic tests, or on other generally acceptable definitive tests consistent with the prevailing state of medical knowledge and clinical practice.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have a manifestation of HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your manifestation of HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your manifestation of HIV infection and provide the results.

3. *Disorders associated with HIV infection (114.11A–E).*

a. *Multicentric Castleman disease* (MCD, 114.11A) affects multiple groups of lymph nodes and organs containing lymphoid tissue. This widespread involvement distinguishes MCD from *localized* (or unicentric) Castleman disease, which affects only a single set of lymph nodes. We require characteristic findings on microscopic examination of the biopsied lymph nodes to establish the diagnosis.

b. *Primary central nervous system lymphoma* (PCNSL, 114.11B) originates in the brain, spinal cord, meninges, or eye. Imaging tests (for example, MRI) of the brain, while not diagnostic, may show a single lesion or multiple lesions in the white matter

of the brain. We require characteristic findings on microscopic examination of the cerebral spinal fluid or of the biopsied brain tissue to establish the diagnosis.

c. *Primary effusion lymphoma* (PEL, 114.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ to establish the diagnosis.

d. *Progressive multifocal leukoencephalopathy* (PML, 114.11D) is a progressive neurological degenerative syndrome caused by the JC virus in immunosuppressed children. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebral spinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus to establish the diagnosis.

e. *Pulmonary Kaposi sarcoma* (Kaposi sarcoma in the lung, 114.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, the gastrointestinal tract) have a more variable prognosis. We require characteristic findings on microscopic examination of the induced sputum or bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, to establish the diagnosis.

4. *CD4 measurement (114.11F).* To evaluate your HIV infection under 114.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count), for children from age 5 to attainment of age 18, or your CD4 percentage, for children from birth to attainment of age 5. This measurement (absolute CD4 count or CD4 percentage) must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one CD4 measurement within this period, we will use your lowest absolute CD4 count or CD4 percentage.

5. *Growth failure due to HIV immune suppression.* We evaluate linear growth failure under a growth impairment listing in 100.00. If your growth failure does not meet or medically equal the criteria of a listing in 100.00, we will consider whether your HIV infection meets or medically equals the criteria of a listing in another body system. For example, if your HIV infection has resulted in weight loss or a combination of weight loss and linear growth failure, we will evaluate your impairment under a digestive system listing in 105.00.

6. *Complications of HIV infection requiring hospitalization (114.11G).*

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and *Pneumocystis* pneumonia and other severe infections.

b. Under 114.11G, we require three hospitalizations within a 12-month period resulting from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review.

7. *Neurological manifestations specific to children (114.11H).* The methods of identifying and evaluating neurological manifestations may vary depending on a child's age. For example, in an infant, impaired brain growth can be documented by a decrease in the growth rate of the head. In an older child, impaired brain growth may be documented by brain atrophy on a CT scan or MRI. Neurological manifestations in infants and young children may present in the loss of acquired developmental milestones (developmental regression) or, in school-age children and adolescents, the loss of acquired intellectual abilities. A child may demonstrate loss of intellectual abilities by a decrease in IQ scores, by forgetting information previously learned, by inability to learn new information, or by a sudden onset of a new learning disability. When infants and young children present with serious developmental delays (without regression), we evaluate the child's impairment(s) under 111.00.

* * * * *

114.11 *Human immunodeficiency virus (HIV) infection.* With documentation as described in 114.00F1 and one of the following:

A. Multicentric Castleman disease (see 114.00F3a). OR

B. Primary central nervous system lymphoma (see 114.00F3b). OR

C. Primary effusion lymphoma (see 114.00F3c). OR

D. Progressive multifocal leukoencephalopathy (see 114.00F3d). OR

E. Pulmonary Kaposi sarcoma (see 114.00F3e). OR

F. Absolute CD4 count or CD4 percentage (see 114.00F4):

1. For children from birth to attainment of age 5, CD4 percentage of less than 15 percent; or

2. For children age 5 to attainment of age 18, absolute CD4 count of 50 cells/mm^3 or less. OR

G. Complications(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 114.00F6). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. OR

H. A neurological manifestation of HIV infection (for example, HIV encephalopathy or peripheral neuropathy) (see 114.00F7) resulting in one of the following:

1. Loss of previously acquired developmental milestones or intellectual ability (including the sudden onset of a new learning disability), documented on two examinations at least 60 days apart; or

2. Progressive motor dysfunction affecting gait and station or fine and gross motor skills, documented on two examinations at least 60 days apart; or

3. Microcephaly with head circumference that is less than the third percentile for age, documented on two examinations at least 60 days apart; or

4. Brain atrophy, documented by appropriate medically acceptable imaging.

[FR Doc. 2014–04124 Filed 2–25–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2013–N–0402]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public hearing into account in developing the fiscal year (FY) 2015 Regulatory Science Plan.

DATES: The public hearing will be held on May 16, 2014, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Thushi Amini, Center for Drug Evaluation and Research, Food and

Drug Administration, 7520 Standish Pl., MPN–1, Rm. 1444, Rockville, MD 20855, 240–276–8810, email: *Thushi.Amini@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., MPN–1, Rm. 1449, Rockville, MD 20855, 240–276–8619, email: *Robert.Lionberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Webcast (see *Streaming Webcast of the Public Hearing*)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments by email to *GDUFARegulatoryScience@fda.hhs.gov* by April 25, 2014. The email should contain complete contact information for each attendee (i.e., name, title, affiliation, address, email address, and telephone number). Those without email access can register by contacting Thushi Amini by April 25, 2014 (see *Contact Person*).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address (see section IV). This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to *GDUFARegulatoryScience@fda.hhs.gov* on or before May 9, 2014. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and other background materials will be made available 5 days before the hearing at *http://www.fda.gov/Drugs/NewsEvents/ucm344710.htm.*

If you need special accommodations because of a disability, please contact Thushi Amini (see *Contact Person*) at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live Webcast of the hearing. To join the hearing via the Webcast, please go to *https://collaboration.fda.gov/regscipart15/.*

Comments: Regardless of attendance at the public hearing, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), 5600 Fishers Lane, Rm. 1061, Rockville, MD 20857. The deadline for submitting comments to the docket is June 13, 2014. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may also be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and reduce costs to industry. To support this goal, FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012–2017. The commitment letter can be found at *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.*

II. FY 2013 Regulatory Science Priorities

The FY 2013 regulatory science research priorities list was developed by FDA and industry and included in the GDUFA commitment letter. To implement the FY 2013 priorities list, the Office of Generic Drugs awarded $17 million in external contracts and grants to initiate new research studies during FY 2013. Four million dollars were allocated to support internal research related to generic drugs. This includes rapid response capabilities through equipment for FDA labs and support for laboratory research fellows at FDA, as well as research fellows to work on data analysis and coordination of internal activities with external grants and contracts.

III. FY 2014 Regulatory Science Priorities

On June 21, 2013, the Office of Generic Drugs held a public hearing to gain input in developing the FY 2014 regulatory science priorities list. This list was prepared based on internal Center for Drug Evaluation and Research discussions, comments received from this public hearing, and comments submitted to the public docket.

The FY 2014 Regulatory Science Priorities are as follows:

1. Postmarket evaluation of generic drugs,
2. Equivalence of complex products,
3. Equivalence of locally acting products,
4. Therapeutic equivalence evaluation and standards, and
5. Computational and analytical tools.

For more information on these topic areas, please visit *http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm370952.htm.*

IV. Purpose and Scope of the May 16, 2014, Public Hearing

The purpose of the May 2014 public hearing is to obtain input from industry and other interested stakeholders on the identification of regulatory science priorities for FY 2015. To help fulfill FDA's mission, FDA is particularly interested in receiving input on the following topics:

1. Current regulatory science challenges that limit the availability of generic drugs,
2. Regulatory science approaches to improve the preapproval evaluation of therapeutic equivalence of generic drugs,
3. Postapproval regulatory science approaches to ensure the therapeutic equivalence of approved generic drugs,
4. Prioritization of FY 2015 regulatory science research topics for generic drugs based on public health impact, and
5. The need for additional or revised draft guidance to clarify FDA's scientific recommendations related to generic drug development.

FDA will consider all comments made at this hearing or received through the docket (see *Comments*) as it develops its FY 2015 GDUFA Regulatory Science Plan. Additional information concerning GDUFA, including the text

of the law and the commitment letter can be found on the FDA Web site at *http://www.fda.gov/gdufa*.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR Part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C) (21 CFR Part 10, subpart C)). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03986 Filed 2–25–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2014–0003; Notice No. 142]

RIN 1513–AC05

Proposed Establishment of The Rocks District of Milton–Freewater Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the approximately 3,770-acre ''The Rocks District of Milton–Freewater'' viticultural area in Umatilla County, Oregon. The proposed viticultural area lies entirely within the Walla Walla Valley viticultural area which, in turn, lies within the Columbia Valley viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on this proposed addition to its regulations.

DATES: Comments must be received by April 28, 2014.

ADDRESSES: Please send your comments on this notice to one of the following addresses:

- *Internet: http://www.regulations.gov* (via the online comment form for this notice as posted within Docket No. TTB–2014–0003 at ''Regulations.gov,'' the Federal e-rulemaking portal);
- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or
- *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice, selected supporting materials, and any comments that TTB receives about this proposal at *http://www.regulations.gov* within Docket No. TTB–2014–0003. A link to that docket is posted on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 142. You also may view copies of this notice, all related petitions, maps, or other supporting materials, and any comments that TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. Please call 202–453–2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated December 10, 2013, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Part 4 of the TTB regulations (27 CFR Part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR Part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and a name and a delineated boundary as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs.

Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;
- A copy of the appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

The Rocks District of Milton–Freewater Petition

TTB received a petition from Dr. Kevin R. Pogue, a professor of geology at Whitman College in Walla Walla, Washington, proposing the establishment of the ''The Rocks District of Milton–Freewater'' AVA in Umatilla County, Oregon, near the town of Milton–Freewater. The proposed AVA lies entirely within the Walla Walla Valley AVA (27 CFR 9.91), which is located in portions of Walla Walla County, Washington and Umatilla County, Oregon. The Walla Walla Valley AVA is, in turn, entirely within the larger Columbia Valley AVA (27 CFR 9.74), which is located in multiple counties in Washington and Oregon. The proposed AVA contains approximately 3,770 acres and has approximately 250 acres of commercially producing vineyards. The petition names 19 wine producers that have vineyards within the proposed AVA, and it notes that three of the 19 producers also have winery facilities within the proposed AVA. According to the petition, the distinguishing feature of the proposed The Rocks District of Milton–Freewater AVA is its soil. Unless otherwise noted, all information and data pertaining to the proposed AVA contained in this document are from the petition for the proposed The Rocks District of Milton–Freewater AVA and its supporting exhibits.

Name Evidence

The proposed The Rocks District of Milton–Freewater AVA is located on an alluvial fan of the Walla Walla River and derives its name from the cobblestone-rich soil near the town of Milton–Freewater, Oregon. The towns of Milton and Freewater were founded in the late 1800s and merged in 1951 to become Milton–Freewater. A 1906 magazine article included as part of the petition demonstrates that the region of the proposed AVA has long been associated with its unusually rocky soil. The article states, ''I wonder if you ever thought of how Freewater appears to a stranger? . . . 'Rocks! Rocks!' I hear you say.'' [1] The article notes that, in spite of the rocky soil, ''[t]he fruit trees are growing here in abundance,'' as are ''luscious clusters of grapes . . ..''

Excerpts from recent articles published on wine industry Web sites and blogs provide evidence that the location of the proposed AVA is commonly referred to as ''The Rocks.'' Three of the articles are from wine reviewer Sean P. Sullivan's Washington Wine Report Web site. (See *www.wawinereport.com.*) The first article, from April 2, 2010, states, ''The Rocks area is located on a historic, cobblestone-strewn riverbed.'' [2] The second article, posted on September 12, 2012, features a vineyard owner who purchased property within the proposed AVA because of ''the potential in the Rocks.'' [3] The third article, posted on September 19, 2012, refers to ''the Rocks region, the ancient cobblestone riverbed in the southern section of the valley.'' [4]

Two articles by Kori Voorhees from the Wine Peeps wine blog also provide evidence that the region of the proposed AVA is known as ''The Rocks.'' (See *www.winepeeps.com.*) The first article, from November 8, 2010, describes a vineyard within the proposed AVA as being ''located near Milton–Freewater, Oregon, in an area known as The Rocks.'' [5] The second article, from June 13, 2012, states that another vineyard within the proposed AVA is situated ''in an area called 'The Rocks' by the locals.'' [6]

Several excerpts from the writings of Paul Gregutt, a wine writer who focuses on wines from Oregon and Washington, refer to the region of the proposed AVA as ''The Rocks.'' Three excerpts are from his book *Washington Wines and Wineries: The Essential Guide,* which also includes information on the region of the proposed AVA because the existing Walla Walla Valley and Columbia Valley AVAs that encompass it cover portions of both Washington and Oregon. The first excerpt notes that the vineyards of the proposed AVA are ''scattered throughout the old riverbed informally known as the Rocks.'' The second excerpt states, ''The area known locally as the Rocks, located in Oregon west of Milton–Freewater . . . was first planted to wine grapes in the late 1990's.'' The third excerpt describes a vineyard within the proposed AVA that has ''12 acres planted in the Rocks to cabernet franc, malbec, syrah, and tempranillo.'' Finally, an article from Mr. Gregutt's wine blog posted on April 11, 2011, describes a newly planted vineyard within the proposed AVA as ''a new addition in The Rocks.'' [7] (See *www.paulgregutt.com.*)

The United States Geological Survey's (USGS) Geographical Names Information System (GNIS; *http://geonames.usgs.gov/index.html*) lists 25 locations in the United States known as ''The Rocks.'' Therefore, the petitioner added ''Milton–Freewater'' to the proposed name in order to distinguish the proposed AVA from the other locations. The town of Milton–Freewater is located partially within the proposed AVA and is clearly identified on the Milton–Freewater USGS quadrangle map used to mark the boundary of the proposed AVA. A GNIS search for ''Milton–Freewater'' conducted by TTB produced 15 results, all of which are for locations within the town of Milton–Freewater, Oregon, including a post office, a Department of Motor Vehicles office, a library, a municipal court, a sewage treatment plant, and several fire stations.

Boundary Evidence

As previously noted, the proposed The Rocks District of Milton–Freewater AVA lies entirely within the Oregon portion of the existing Walla Walla Valley AVA, which, in turn, lies entirely within the existing Columbia Valley AVA. The proposed AVA does not overlap with any other existing or proposed AVA.

The proposed The Rocks District of Milton–Freewater AVA is located on an alluvial fan of the Walla Walla River where the river exits the foothills of the Blue Mountains and enters the Walla Walla Valley. The proposed boundary follows a series of straight lines between points marked on the relevant USGS maps to encompass the central portion of the alluvial fan, which features the

[1] George B. Sanderson, ''Outsider's View of Freewater,'' Up-To-The-Times, December 1906, page 31.

[2] ''Washington's 'Dirty Little Secret'—Some of Our Best Wines are From Oregon Grapes.''

[3] ''Proper Wines–From the Rocky Mountains to the Rocks of Walla Walla Valley.''

[4] ''Delmas—How One Little Vacation Can Change Your Life.''

[5] ''Cayuse: Unique Terroir or Flawed Wine?''

[6] ''Watermill Winery: Great Fruit and Great Wines From the Brown Family.''

[7] ''New From Figgins Family Wineries.''

heavily cobbled Freewater series soil that is the defining characteristic of the proposed AVA. The petition notes that the proposed boundary was drawn to include as much of the heavily cobbled soils as possible while minimizing the inclusion of other soils. However, because the proposed boundary is required to be drawn using features found on the USGS maps, some relatively small areas of non-cobbled soil may be incorporated into the proposed AVA and some small areas of cobbled soil may be excluded.

Distinguishing Feature

The distinguishing feature of the proposed The Rocks District of Milton–Freewater AVA is the cobblestone-rich soil. In the original Soil Survey of Umatilla County, published by the United States Department of Agriculture in 1948, the cobblestone soils were mapped within the Yakima series as Yakima cobbly loam and Yakima gravelly loam. In 1985, these soils were reclassified within the newly created Freewater series as Freewater very cobbly loam and Freewater gravely silt loam. The region of cobblestone-rich soils that is covered by the town of Milton–Freewater was reclassified as Freewater–Urban land complex. According to the petition, 96 percent of the proposed AVA is covered by soils of the Freewater series.

Soils of the Freewater series are comprised mainly of basaltic alluvium derived from the erosion of the Blue Mountains, located to the east of the proposed AVA. Over time, the Walla Walla River and its numerous branches have carried gravel, cobbles, and boulders of basalt from the Blue Mountains into the Walla Walla Valley. As these pieces of rock built up in the river and its branches, the streams became shallower and changed their courses, leaving the rocks behind to form a broad alluvial fan. The gravel, cobbles, and boulders in the alluvial fan are loose and uncemented and form very deep layers. In areas that have not been tilled for cultivation, the stones are covered with a very thin layer of fine, windblown alluvium called loess. However, in areas that have been tilled, the stones are very conspicuous. The petition included photographs of several vineyards within the proposed AVA which show the vines planted in fields covered so completely with rocks that they have the appearance of cobblestone streets.

The soils in the regions surrounding the proposed The Rocks District of Milton–Freewater AVA are largely of the Walla Walla, Ellisforde, Yakima, Umapine, Hermison, Onyx, and Oliphan series. Classified as silt loams, cobbles are uncommon or absent from these soils, which were formed mainly from loess and are largely granite-derived, in contrast with the basalt-derived soils of the Freewater series. In parts of the surrounding regions outside the proposed AVA, the soils are underlain by ''Touchet beds,'' dense layers of sand and silt deposited by prehistoric floods. Touchet beds do not occur within the proposed AVA.

The excessively stony nature of the soils affects grape growing within the proposed The Rocks District of Milton–Freewater AVA. Because the stones that comprise the soils are uncemented and occur in deep layers, the vines are able to send roots between the stones and extend deep into the ground before being stopped by bedrock or cemented gravel. According to the petition, a root would have to penetrate 30 to 50 feet before reaching either bedrock or a denser layer of cemented gravel, which is deeper than grapevine roots typically grow. Deeply rooted vines can reach moisture stored in deep layers of the soil and therefore are more drought-tolerant than vines with shallower root systems. The petition states that although the soils in the surrounding region vary in thicknesses, they are generally not as deep as the Freewater series soils. As a result, vines planted outside the proposed AVA are not able to penetrate as deeply before hitting bedrock, Touchet beds, or a layer of cemented gravel.

The rockiness of the soils within the proposed AVA allows water to drain freely, which inhibits mildew and rot. According to the petition, Freewater series soils transmit water at rates in excess of 20 inches an hour, which classifies the soils as ''somewhat excessively drained.'' The soils surrounding the proposed AVA, by contrast, have finer grains that are packed more closely together, allowing them to drain water at the much slower rate of less than 2 inches per hour.

The soils of the proposed The Rocks District of Milton–Freewater AVA have a low risk of erosion because they are not comprised of fine, lightweight particles that could easily be removed by wind or rain. Because the soils are so resistant to erosion, vineyard owners can till repeatedly during the growing season. According to the petition, tilling concentrates the larger rocks on the surface, where they form a natural barrier to weed growth. The soils surrounding the proposed AVA, however, cannot be tilled as frequently because the soils are finer and more susceptible to erosion. As a result, vineyard owners outside the proposed AVA often plant ground cover crops between the rows of vines in order to suppress the growth of weeds and prevent erosion.

The rocky soil of the proposed AVA also absorbs and stores solar radiation. During the day, the sun heats the soil enough to raise both the surface and subsurface soil temperatures, as well as the temperature of low-hanging grape clusters. The petition included the results of a study comparing the surface and subsurface soil temperatures and the temperature of low-hanging clusters of grapes in a vineyard with the Freewater series soil and a vineyard with grass-covered loess soil. The data shows that the surface soil, subsurface soil, and grape cluster temperatures were all warmer in the vineyard with the Freewater series soil. The greatest temperature difference was at the surface of the soil, where temperatures in the rocky vineyard were approximately 4.5 degrees Celsius warmer than in the vineyard with the grass-covered loess soil. During the day, the warming of the stony Freewater series soil promotes vine growth, fruit maturation, and efficient photosynthesis. At night, the soil slowly releases the stored heat and warms the air enough to reduce the risk of frost in late spring and early fall.

Finally, the Freewater series soils of the proposed AVA have higher concentrations of certain elements than the soils of the surrounding regions. The petition includes a chemical analysis of the most common Freewater series soil, Freewater very cobbly loam, and the most common soil of the surrounding region, Walla Walla silt loam. The Freewater very cobbly loam contains significantly higher amounts of calcium, titanium, and iron than the Walla Walla silt loam. The petition also includes a comparison of the amount of iron in the soil that is in a form that can be used by plants. The plant-available iron level found in the vineyard within the proposed AVA was approximately 72 milligrams per kilogram (mg/kg). By contrast, the highest level of plant-available iron found in the surrounding region was approximately 45 mg/kg. Calcium, titanium, and especially iron are nutrients that are critical for healthy vine growth and fruit development.

Comparison of the Proposed the Rocks District of Milton–Freewater AVA to the Existing Walla Walla Valley and Columbia Valley AVAs

Walla Walla Valley AVA

The Walla Walla Valley AVA was established by T.D. ATF–165, which published in the **Federal Register** on

February 6, 1984 (49 FR 4374). The Walla Walla AVA's boundary was later modified so that the entire AVA lay within the larger Columbia Valley AVA (see T.D. ATF–441, published in the **Federal Register** on February 26, 2001, at 66 FR 11542). The Walla Walla Valley AVA covers portions of Walla Walla County in southeast Washington and Umatilla County in northeast Oregon.

According to T.D. ATF–165 and T.D. ATF–441, the Walla Walla Valley AVA is a broad valley cut by the Walla Walla River. It is bordered by the mountainous Umatilla National Forest to the southeast, the Touchet River watershed to the north, and the Columbia River to the west. Elevations range from approximately 500 feet to 1,500 feet. The soils within the AVA are primarily derived from loess. The Walla Walla Valley AVA has a growing season of between 190 and 220 days and receives an average of 12.5 inches of rain annually.

The proposed The Rocks District of Milton–Freewater AVA is located entirely within the portion of the Walla Walla Valley AVA that is located within Umatilla County, Oregon, and it shares some broad characteristics of the larger established AVA. The proposed The Rocks District of Milton–Freewater AVA has a climate similar to that of the Walla Walla Valley AVA, with a growing season of approximately 197 days and an average rainfall of approximately 14 inches. Additionally, elevations in the proposed AVA are between 850 and 1,000 feet, which is within the range of elevations within the Walla Walla Valley AVA. However, the lowest elevations within the proposed AVA are higher than the lowest elevations of the Walla Walla Valley AVA and are not as susceptible to frost and freeze risks related to nocturnal temperature inversions that frequently affect the lower elevations of the Walla Walla Valley AVA. Furthermore, in contrast to the fine-grained, loess-derived soils of the Walla Walla Valley AVA, the soils within the proposed AVA are basalt-derived and contain large amounts of gravel, cobbles, and boulders. As previously discussed, the rocky soils of the proposed AVA contain higher levels of essential nutrients, are less prone to erosion, drain more rapidly, and absorb and radiate more solar energy than loess-derived soils.

Columbia Valley AVA

The Columbia Valley AVA was established by T.D. ATF–190, which published in the **Federal Register** on November 13, 1984 (49 FR 44895). The Columbia Valley AVA is a large basin surrounding the Columbia, Snake, and Yakima Rivers in Washington and Oregon. T.D. ATF–190 states that the Columbia Valley AVA has a growing season of between 150 and 204 days and annual rainfall of less than 15 inches.

The proposed The Rocks District of Milton–Freewater AVA is located entirely within the Oregon portion of the Columbia Valley AVA and has a climate similar to that of the Columbia Valley AVA. However, the distinctive rocky soil of the proposed AVA distinguishes it from the larger Columbia Valley AVA. Although T.D. ATF–190 does not describe the soil of the Columbia Valley AVA, a soil series description included in the petition to establish the proposed The Rocks District of Milton–Freewater AVA notes that the major soil series of the proposed AVA, the Freewater series, ''is of small extent'' and is essentially limited to Umatilla County, Oregon.

TTB Determination

TTB concludes that the petition to establish the approximately 3,770-acre The Rocks District of Milton–Freewater AVA merits consideration and public comment, as invited in this notice.

Boundary Description

See the narrative boundary description of the petitioned-for AVA in the proposed regulatory text published at the end of this notice.

Maps

The petitioner provided the required maps, and they are listed below in the proposed regulatory text.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. If TTB establishes this proposed AVA, its name, ''The Rocks District of Milton–Freewater,'' will be recognized as a name of viticultural significance under 27 CFR 4.39(i)(3). TTB has also determined that the phrase ''The Rocks of Milton–Freewater'' has viticultural significance in relation to the proposed AVA. The text of the proposed regulation clarifies this point. Consequently, wine bottlers using the name ''The Rocks District of Milton–Freewater'' or ''The Rocks of Milton–Freewater'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, would have to ensure that the product is eligible to use the AVA name as an appellation of origin if this proposed rule is adopted as a final rule. TTB does not believe that either ''The Rocks'' or ''The Rocks District,'' standing alone, would have viticultural significance if the proposed AVA is established, due to the widespread use of ''The Rocks'' as a geographical name. GNIS shows the name ''The Rocks'' used in reference to 25 locations in 17 States within the United States. Accordingly, the proposed part 9 regulatory text set forth in this document specifies only the full name ''The Rocks District of Milton–Freewater'' and the phrase ''The Rocks of Milton–Freewater'' as terms of viticultural significance for purposes of part 4 of the TTB regulations.

The approval of the proposed The Rocks District of Milton–Freewater AVA would not affect any existing AVA, and any bottlers using ''Walla Walla Valley'' or ''Columbia Valley'' as an appellation of origin or in a brand name for wines made from grapes grown within the Walla Walla Valley or Columbia Valley AVAs would not be affected by the establishment of this new AVA. The establishment of the proposed The Rocks District of Milton–Freewater AVA would allow vintners to use ''The Rocks District of Milton–Freewater,'' ''Walla Walla Valley,'' and ''Columbia Valley'' as appellations of origin for wines made from grapes grown within the proposed The Rocks District of Milton–Freewater AVA if the wines meet the eligibility requirements for the appellation.

For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label.

Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

Public Participation

Comments Invited

TTB invites comments from interested members of the public on whether it should establish the proposed AVA. TTB is also interested in receiving comments on the sufficiency and accuracy of the name, boundary, soils, and other required information submitted in support of the petition. In

addition, given the proposed The Rocks District of Milton–Freewater AVA's location within the existing Walla Walla Valley and Columbia Valley AVAs, TTB is interested in comments on whether the evidence submitted in the petition regarding the distinguishing features of the proposed AVA sufficiently differentiates it from the existing Walla Walla Valley and Columbia Valley AVAs. TTB is also interested in comments on whether the geographic features of the proposed AVA are so distinguishable from the surrounding Walla Walla Valley and Columbia Valley AVAs that the proposed The Rocks District of Milton–Freewater AVA should no longer be part of those AVAs. Please provide specific information in support of your comments.

Because of the potential impact of the establishment of the proposed The Rocks District of Milton–Freewater AVA on wine labels that include the term ''The Rocks District of Milton–Freewater'' or ''The Rocks of Milton–Freewater'' as discussed above under Impact on Current Wine Labels, TTB is particularly interested in comments regarding whether there will be a conflict between the proposed AVA name and currently used brand names. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed AVA will have on an existing viticultural enterprise. TTB is also interested in receiving suggestions for ways to avoid conflicts, for example, by adopting a modified or different name for the AVA.

Impact on Wines Produced Across State Lines

Section 4.25(e)(3)(iv) of the TTB regulations (27 CFR 4.25(e)(3)(iv) requires that wines labeled with an AVA appellation of origin be ''fully finished within the State, or one of the States, within which the labeled viticultural area is located . . .'' The proposed The Rocks District of Milton–Freewater AVA is located entirely within Oregon, but is only a few miles from Walla Walla, Washington. TTB is aware that there may be winemakers who use custom crush or alternating proprietor facilities located in Walla Walla to make wine primarily from grapes grown within the proposed AVA. TTB understands winemakers may be using these facilities because of a lack of custom crush or alternating proprietor facilities located nearby in Oregon. Because of the TTB regulation, if the proposed The Rocks District of Milton–Freewater AVA is established, winemakers who use facilities in the State of Washington to produce wine from grapes grown within the proposed AVA would be unable to use ''The Rocks District of Milton–Freewater'' as an appellation of origin on their labels. TTB is interested in comments from persons who believe they may be negatively impacted by the inability to use ''The Rocks District of Milton–Freewater'' as an appellation of origin on a wine label solely because they use facilities located in Washington.

Submitting Comments

You may submit comments on this notice by using one of the following three methods:

- *Federal e-Rulemaking Portal:* You may send comments via the online comment form posted with this notice within Docket No. TTB–2014–0003 on ''Regulations.gov,'' the Federal e-rulemaking portal, at *http://www.regulations.gov.* A direct link to that docket is available under Notice No. 142 on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml.* Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on the ''Help'' tab.
- *U.S. Mail:* You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.
- *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 142 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as originals.

In your comment, please clearly state if you are commenting for yourself or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity's name as well as your name and position title. If you comment via Regulations.gov, please enter the entity's name in the ''Organization'' blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

TTB will post, and you may view, copies of this notice, selected supporting materials, and any online or mailed comments received about this proposal within Docket No. TTB–2014–0003 on the Federal e-rulemaking portal, Regulations.gov, at *http://www.regulations.gov.* A direct link to that docket is available on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 142. You may also reach the relevant docket through the Regulations.gov search page at *http://www.regulations.gov.* For information on how to use Regulations.gov, click on the site's ''Help'' tab.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that the Bureau considers unsuitable for posting.

You may also view copies of this notice, all related petitions, maps and other supporting materials, and any electronic or mailed comments that TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. You may also obtain copies at 20 cents per 8.5 x 11-inch page. Please note that TTB is unable to provide copies of the USGS quadrangle maps or any similarly sized documents that may be included as part of the AVA petition. Contact TTB's information specialist at the above address or by telephone at 202–453–2270 to schedule an appointment or to request copies of comments or other materials.

Regulatory Flexibility Act

TTB certifies that this proposed regulation, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed regulation imposes no

new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this notice of proposed rulemaking.

List of Subjects in 27 CFR Part 9

Wine.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, TTB proposes to amend title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9._____to read as follows:

§ 9._____ The Rocks District of Milton–Freewater.

(a) *Name.* The name of the viticultural area described in this section is ''The Rocks District of Milton–Freewater''. For purposes of part 4 of this chapter, ''The Rocks District of Milton–Freewater'' and ''The Rocks of Milton–Freewater'' are terms of viticultural significance.

(b) *Approved maps.* The two United States Geological Survey 1:24,000 scale topographic maps used to determine the boundary of The Rocks District of Milton–Freewater viticultural area are titled:

(1) Milton–Freewater, Oreg., 1964; and

(2) Bowlus Hill, Oreg., 1964; photoinspected 1976.

(c) *Boundary.* The Rocks District of Milton–Freewater viticultural area is located in Umatilla County, Oregon. The boundary of The Rocks District of Milton–Freewater viticultural area is as follows:

(1) The beginning point is found on the Milton–Freewater map at the intersection of an unnamed medium-duty road known locally as Freewater Highway (State Route 339) and an unnamed light-duty road known locally as Crockett Road, section 26, T6N/R35E. From the beginning point, proceed east-southeasterly in a straight line for 0.8 mile to the intersection of State Highway 11 (Oregon–Washington Highway) and an unnamed light-duty road known locally as Appleton Road, section 25, T6N/R35E; then

(2) Proceed southeasterly in a straight line for 1.05 miles, crossing onto the Bowlus Hill map, to the intersection of three unnamed light-duty roads known locally as Grant Road, Turbyne Road, and Pratt Lane on the common boundary between section 36, T6N/R35E, and section 31, T5N/R36E; then

(3) Proceed southwesterly in a straight line for 1.1 miles, crossing back onto the Milton–Freewater map, to the intersection of the Union Pacific railroad tracks with the Walla Walla River, section 1, T5N/R35E; then

(4) Proceed southwesterly and then west-northwesterly along the Union Pacific railroad tracks for 1.2 miles to the intersection of the railroad tracks with the 980-foot elevation contour line, approximately 0.15 mile west of Lamb Street, section 2, T5N/R35E; then

(5) Proceed west-northwesterly in a straight line for 2.25 miles to the intersection of the 840-foot elevation contour line and an unnamed light-duty road known locally as Lower Dry Creek Road, section 33, T6N/R35E; then

(6) Proceed northwesterly in a straight line for 0.8 mile to the intersection of the 800-foot elevation contour line with an unnamed light-duty road running north-south in section 32, T6N/R35E; then

(7) Proceed easterly in a straight line for 0.9 mile to the intersection of the 840-foot elevation contour line with the Hudson Bay Canal, section 33, T6N/R35E; then

(8) Proceed due north in a straight line for 0.25 mile to the line's intersection with Sunnyside Road, section 33, T6N/T35E; then

(9) Proceed northeasterly in a straight line for 0.5 mile to the intersection of the 840-foot elevation contour line with an unnamed medium-duty road known locally as State Highway 332 (Umapine Highway), eastern boundary of section 28, R6N/T35E; then

(10) Proceed east-northeasterly in a straight line for 0.3 mile to the intersection of three unnamed light-duty roads known locally as Triangle Road, Hodgen Road, and Appleton Road, section 27, T6N/R35E; then

(11) Proceed east-northeasterly in a straight line for 1.25 miles, returning to the beginning point.

Signed: February 20, 2014.

John J. Manfreda,

Administrator.

[FR Doc. 2014–04137 Filed 2–25–14; 8:45 am]

BILLING CODE 4810–31–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Parts 101, 102, 103

RIN 3142–AA08

Representation-Case Procedures

AGENCY: National Labor Relations Board.

ACTION: Proposed rule; notice of meeting.

SUMMARY: The National Labor Relations Board (NLRB or Board) invites interested persons to attend a public meeting of the Board on April 10 and 11. The Board meeting will start at 9:30 a.m. on each day. The meeting will be held in the Margaret A. Browning Hearing Room (Room 11000), National Labor Relations Board, 1099 14th Street NW., Washington, DC 20570. During the meeting, persons who have previously requested to speak may share their views on the proposed amendments to the Board's rules governing representation case procedures, published at 79 FR 7318, and make other proposals for improving representation case procedures.

DATES: The meeting will be held on April 10 and 11, 2014, starting at 9:30 a.m. on each day. Additional days of meeting may be scheduled for April 8 and/or 9. Those who wish to speak at the meeting must submit a Request to Speak, in the form described in the instructions below, which must be received by the Board no later than March 10, 2014. In addition, due to seating considerations, persons desiring to attend the meeting must submit a Request to Attend, which must be received by the Board no later than March 31, 2014. Those who Request to Speak need not also submit a Request to Attend.

ADDRESSES: The public meeting will be held in the Margaret A. Browning Hearing Room (Room 11000), National Labor Relations Board, 1099 14th Street NW., Washington, DC 20570. Requests to Speak and Requests to Attend must be addressed to Gary Shinners, Executive Secretary, 1099 14th Street NW., Suite 11600, Washington, DC 20570. Alternatively, written requests

may be submitted electronically to *publicmeeting@nlrb.gov*. All requests must include the following words on the Subject Line—''Request to Attend Public Meeting RIN 3142–AA08,'' or ''Request to Speak at Public Meeting RIN 3142–AA08.''

FOR FURTHER INFORMATION CONTACT: Gary Shinners, Executive Secretary, National Labor Relations Board, 1099 14th Street NW., Suite 11600, Washington, DC 20570, (202) 273–3737 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION: The National Labor Relations Board will hold an open public meeting on April 10 and 11, 2014 starting at 9:30 a.m. on each day. Additional days of meeting may be scheduled for April 8 and/or 9. Pursuant to 5 U.S.C. 553(c), the purpose of the meeting will be to allow interested persons to participate in the rulemaking through oral presentation on the proposed amendments to the Board's rules governing representation-case procedures and to make any other proposals for improving representation case procedures.

The Board intends to give members of the public a fair opportunity to address the issues listed below, subject to the Board's discretion to both ask questions of speakers and to avoid repetitious or cumulative subject matter. The hearing may be organized by topic(s) into multiple sessions, as noted below. This may result in some oral presentations being split into multiple parts, possibly requiring participation in more than one session. Depending on Requests to Speak received by the Board (see below), some requests to address several issues at the same time may be granted. For any single session, it is anticipated that the initial time allotted to a particular presenter will be at least four minutes. Speakers who are to address several issues at the same session may be initially allotted substantially more time for their overall presentation, at the Board's discretion. (As noted above, in some cases such a presentation may be split into multiple parts, possibly requiring an appearance in more than one session.) Determinations to grant or deny Requests to Speak, and of the allotment of time for oral presentations shall be subject to the discretion of the Board.

On February 6, 2014, the NLRB published a Notice of Proposed Rulemaking, proposing to amend its rules and regulations governing the filing and processing of petitions relating to the representation of employees for purposes of collective bargaining with their employer. As stated in the NPRM, the NLRB is providing an opportunity for interested persons to request to provide their views to the Board on this important matter at a public meeting.

Persons desiring to attend the meeting must submit a Request to Attend, in writing, at the above-listed address or email address, which must be received by the deadline posted in the **DATES** section above. In this request, potential attendees must specify (1) their full name, (2) their organizational affiliation (if any), and (3) contact information. Due to the potential space limitations in the meeting room, the NLRB will notify persons whether they will be able to attend prior to the meeting. Attendees are reminded to bring a photo identification card with them to the public meeting in order to gain admittance to the building.

Persons desiring to speak at the meeting must submit a Request to Speak, in writing, at the above-listed address or email address, which must be received by the deadline posted in the **DATES** section above. In addition to the information required of attendees, those who wish to speak must also follow the more detailed instructions below.

The primary source of input to be considered by the Board will be the extensive written comments submitted in response to the 2011 proposed rule regarding representation-case procedures, and the written comments submitted in response to the NPRM published in the **Federal Register** on February 6, 2014. Written comments submitted in response to the 2011 proposed rule, or in response to the more recent NPRM, will receive the same consideration without regard to whether the commenters make oral presentations during the public meetings described in this notice. Similarly, decisions regarding the allotment of time for particular oral presentations do not mean the Board will give greater or lesser consideration to particular speakers or commenters. The Board's intention is to structure the public meetings in a manner that will reflect multiple perspectives on relevant issues with a mix of shorter and longer presentations depending on the range of issues and views summarized in Requests to Speak received by the Board.

Instructions for Submitting a Request To Speak

1. A Request to Speak may be submitted on behalf of an individual or an organization. More than one person may submit a Request to Speak on behalf of the same organization. Each such request must be submitted separately.

2. You must designate which of the issues listed below (''Issues'') you wish to address. Be as specific as possible in making your designation. Reference the letter, and, where applicable, the number(s), and sub-part(s) of the issues listed. If you designate issue H (''Other Issues''), you must identify the issue with a sentence or phrase.

3. If you designate more than one issue, please list your designations in order of priority. Begin by listing the issue you most wish to speak about, and continue in order of decreasing priority.

4. Immediately following the designation(s) of issue(s), please summarize for each issue what you wish to say. For your reference, a Sample Request to Speak is also included below.

5. For each issue, your summary is limited to 250 words. You are also limited to a cumulative total of 1,250 words in the document making your request. No motions to exceed this limit will be entertained. Requests to Speak must conform to these requirements to be considered. **Note:** written comments remain the primary means for expressing your views, and there is no word limit on written comments.

In the event that there are more Requests to Speak than there are available time slots, the Board will allocate the available time slots in an effort to insure that individuals and organizations are heard whose remarks appear most likely to be useful to the Board in its deliberations. This determination will be based on the summaries provided in the Requests to Speak. It is likely that not every requester will have the opportunity to speak on every issue requested. It is also anticipated that some issues will generate many substantially similar requests. For this reason, it is suggested that you focus your request on matters on which you possess relevant experience and expertise and about which you may have something unique to say. It is also possible, however, that the Board may ask for your views on matters that you do not designate in your request.

All speakers should be prepared to answer questions from members of the Board. Before the hearing, the Board may also choose to submit questions for discussion related to any of specific issues noted below.

The Board will notify you prior to the meeting whether you will be speaking, the issue(s) you will be called upon to address, the date(s) and time(s) of the session(s) at which you are to speak, and the amount of your initial allotment

of speaking time for each session. As noted above, it is anticipated at this time that initial allotments will be at least four minutes.

Issues

A. *Petitions and Pre-Hearing Issues.* Whether or how procedures should be revised concerning the petition, electronic filing and service, the showing of interest, and employee notices.

1. Whether the petition may be filed electronically.

2. Whether the petitioner should be responsible for service of the petition.

3. Whether the petitioner should be responsible for serving an NLRB form explaining party rights and obligations together with the petition.

4. Whether the petitioner should be required to designate an individual representative for purposes of service.

5. Whether the petitioner should be required to file the showing of interest with the Board at the same time as the petition.

6. Whether electronic signatures should be permitted to satisfy the showing of interest.

7. Whether, upon service of the petition, the employer should be required to post an initial Board notice to the employees describing the petition and procedures.

8. Whether or how the rules should amend the final notice to employees regarding the election.

a. Whether the notice should issue simultaneously with the direction of election.

b. Whether the notice should be distributed electronically, either by the region or by the employer.

c. Whether the time period for posting the final notice should be at least two full working days before the election, three full working days as is the current practice, or some other length of time.

9. Whether the Board should electronically transmit documents to the parties.

B. *Pre-Election Hearings.* Whether or how pre-election litigation procedures should be revised.

1. When the pre-election hearing should be held.

2. Whether, when, or how written statements should be filed raising issues and providing initial disclosures of relevant information. Whether, when, or how written statements may be supplemented, corrected, or changed after they are filed or whether parties should be prohibited from changing the positions taken in their written statements. Whether issues not raised in the written statements should be considered waived.

3. Whether or how the rules should define the types of issues which should be litigated at the pre-election hearing.

a. Existence of a question of representation.

b. The appropriateness of the petitioned-for unit.

c. Eligibility issues impacting large groups of employees (the proposed ''20% rule'').

d. Eligibility issues impacting individuals or small groups of employees.

e. Issues which raise special concerns (guard status, professional status, jurisdiction, etc.).

4. Whether or how the rules should describe the procedure for the hearing officer and regional director to follow in admitting and excluding evidence at the hearing.

5. What deadline should be set for filing subpoenas and motions to quash.

6. Whether or how the rules should specify the standard, form, and timing for presenting concluding statements and arguments, and post-hearing briefs.

7. Whether the rules should permit the direction of election to be issued before a pre-election decision is issued, with a decision to follow.

C. *Voter Eligibility Lists.* Whether or how the rules should address voter lists.

1. Whether the Board's holding in *Excelsior Underwear, Inc.,* 156 NLRB 1236 (1966) and the cases that interpret it should be codified in the rules.

2. Service of voter lists.

a. What deadline should be set for an employer to submit voter lists.

b. Whether and how voter lists should be directly served on the parties by the employer.

3. What information the voter lists should contain, whether *Excelsior* should be updated with modern forms of contact information, and how to strike the correct balance of NLRA, privacy, and other interests.

a. Which types of contact information involve greater or lesser privacy concerns.

b. Whether or how restrictions on use of information should be imposed to address privacy concerns.

c. Whether specific alternatives to voter lists might better serve the interests of the Act, including:

i. Whether employees might be able to opt-out/opt-in to the inclusion of certain information on voter lists.

ii. Whether other means of communication might be created, such as government-hosted electronic forums or emails.

D. *Requests for Review.* Whether or how to amend the process for Board review of the decision and direction of election.

1. When the parties should be required to file a request for Board review of the direction of election.

2. Whether or how the rules should describe the standard the Board will apply in deciding whether to grant a stay of proceedings, and/or interlocutory Board review of the direction of election.

3. Whether a request for review which is not interlocutory should be consolidated with any request for review of post-election decisions by the regional director.

4. Whether the Board should eliminate the authority of regional directors to *sua sponte* transfer cases to the Board for issuance of an initial decision and direction of election.

E. *Timing of Elections.* Whether or how the rules should address the scheduling of the election.

1. Whether the election should be scheduled ''as soon as practicable.''

a. If not, whether the rules should include a minimum or maximum time between the filing of the petition and the election, and if so, how long.

2. Whether the waiting period set forth in current Section 101.21(d) should be eliminated.

3. Whether the proposed rules adequately protect free speech interests.

a. If not, state specifically how the rules should be amended to accommodate those interests or which provisions of the proposed rule should be adopted or rejected.

4. Whether or how the rules should address ''blocking charge'' policy and the procedures used for placing a representation case in abeyance pending the outcome of unfair labor practice charges.

a. Whether current practice should be codified.

b. Whether procedures should be expanded to require an offer of proof and/or witnesses to be provided to the region when requesting an abeyance, and whether the regional director should continue processing the case if the offer is inadequate.

c. What process should be followed while the regional director is investigating a request to hold a representation case in abeyance.

d. Whether the standard should be amended to require the regional director to find probable cause to believe that an unfair labor practice was committed before placing a case in abeyance, or whether some other standard should apply. Whether the standard should be the same for different kinds of unfair labor practice allegations, such as those the Board currently describes Type I and Type II blocking charges.

e. Whether and under what circumstances the current procedure should be replaced with a procedure that does not delay the election, such as:

i. a vote-and-impound procedure, or

ii. reliance solely on other existing procedures, such as motions to dismiss the petition and/or post-election objections.

F. *Post-Election Hearings.* Whether or how post-election hearing procedures should be amended.

1. Whether to codify the existing practice of determining if the hearing is warranted by examining the offer(s) of proof.

2. Whether such offer(s) of proof in support of objections should be filed at the same time as the objection(s).

3. When the post-election evidentiary hearing should be held.

4. Whether the post-election hearing should open with statements of party positions, followed by the same joinder and offers of proof procedures as proposed for pre-election hearings. (See Issue B.2)

G. *Other Post-Election Procedures.* Whether or how post-election Board review procedures should be amended.

1. Whether stipulated elections should be subject to discretionary Board review of post-election decisions by the regional director.

2. Whether, in contested cases, regional directors should be required to issue a final decision and certification concerning the hearing officer's report and recommendation, or may instead choose to transfer the matter to the Board.

3. Whether the current discretionary standard for Board review of the regional director's certification in contested cases should be amended.

H. *Other Issues.*

(Sample) Request To Appear

In the matter: Representation-Case Procedures Rulemaking

RIN 3142–AA08

Name: *Your Name.*

Date: *February 28, 2014.*

Organization (if applicable): *Your Name & Associates, P.L.L.C..*

Issues: *B.6; A.1 & A.9; and G.1 & G.2 & G.3.*

First Issue: B.6.

Summary: I strongly oppose the Board's proposal to eliminate the parties' right to file post hearing briefs to the Regional Director after the close of the pre-election hearing. Although the proposal grants hearing officers discretion to permit the filing of post-hearing briefs, it seems clear that the rule is intended to eliminate the right to file briefs in all but the most complicated cases. However, the pre-election hearing is extremely important in every case because that provides the basis for the regional director to decide what the appropriate unit is for purposes of conducting the election. When I file a brief, I point out the best evidence and cases that support my client's position. No matter how dedicated the people in the regional offices are, and no matter how ''routine'' the case is, it is entirely possible that the regional offices will accidentally miss key testimony or fail to locate key cases that support my client's position. This, in turn, may lead the regional office to mistakenly reject my client's position and direct an election in the wrong unit. If that happens, my client will have to go through the hassle and expense of a second election. I firmly believe maintaining parties' right to file briefs will help eliminate mistakes. The old system worked well, and there is no reason to change it.

Second Issue: A.1 & A.9

Summary: I litigate cases and deal with a variety of agencies on behalf of clients. On a regular basis I file and receive documents electronically. I have never had a problem with electronic filing or service of a document. It makes good sense and saves my clients money. I no longer have to pay the cost of having to ''overnight a document'' so it can be filed by the deadline; instead, I can just electronically file the document with the push of a few buttons. This means I don't have to pass on those costs to my client. I also get documents quicker this way. It's a win win for all the parties and practitioners as well as the government. Accordingly, I strongly support the Board's proposal to allow parties and the Board to electronically file and transmit representation case documents.

Third Issue: G.1 & G.2 & G.3

Summary: I agree with the Board's proposal to require the regional director in contested cases to issue a final decision. In these cases it makes little sense for the Board to hear exceptions directly from the hearing officer, when, in my experience, the regional director is usually quite familiar with the case and the issues presented. And once the regional director has issued a decision, there is no problem with the Board having only discretionary review—as expressly stated in Section 3(b) of the Act. Stipulated cases, however, present an entirely different issue. In these cases, the parties have entered into an agreement predicated on their right to have the Board—not the regional director—decide post-election matters. If, as proposed, the Board eliminates that right, the parties will have less incentive to enter into stipulations. For these reasons, I support the Board's proposed changes to post-election review of contested cases, but not stipulated cases.

Dated: Washington, DC February 20, 2014.

By direction of the Board.

William B. Cowen,

Solicitor.

[FR Doc. 2014–04127 Filed 2–25–14; 8:45 am]

BILLING CODE 7545–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 70, 71 and 98

[EPA–HQ–OAR–2013–0495; FRL–9906–59–OAR]

RIN 2060–AQ91

Standards of Performance for Greenhouse Gas Emissions From New Stationary Sources: Electric Utility Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Data Availability (NODA).

SUMMARY: The EPA is issuing this NODA in support of the proposed rule titled ''Standards of Performance for Greenhouse Gas Emissions From New Stationary Sources: Electric Utility Generating Units'' that was published on January 8, 2014. Through this NODA and the technical support document it references, the EPA solicits comment on its interpretation of the provisions in the Energy Policy Act of 2005, including the federal tax credits contained in that Act, which limit the EPA's authority to rely on information from facilities that received assistance under that Act. The EPA believes those provisions do not alter the EPA's determination in the proposed rule that the best system of emission reduction for new fossil fuel-fired boiler and integrated gasification combined cycle electric utility generating units is partial carbon capture and sequestration.

DATES: Comments must be received on or before Monday, March 10, 2014.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2013–0495, by one of the following methods:

At the Web site http://www.regulations.gov: Follow the instructions for submitting comments.

At the Web site http://www.epa.gov/oar/docket.html: Follow the instructions

for submitting comments on the EPA Air and Radiation Docket Web site.

Email: Send your comments by electronic mail (email) to *a-and-r-docket@epa.gov,* Attn: Docket ID No. EPA–HQ–OAR–2013–0495.

Facsimile: Fax your comments to (202) 566–9744, Attn: Docket ID No. EPA–HQ–OAR–2013–0495.

Mail: Send your comments to the EPA Docket Center, U.S. EPA, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, Attn: Docket ID No. EPA–HQ–OAR–2013–0495. Please include a total of two copies.

Hand Delivery or Courier: Deliver your comments to the EPA Docket Center, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004, Attn: Docket ID No. EPA–HQ–OAR–2013–0495. Such deliveries are accepted only during the Docket Center's normal hours of operation (8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays), and special arrangements should be made for deliveries of boxed information.

Instructions: All submissions must include the agency name and docket ID number (EPA–HQ–OAR–2013–0495). The EPA's policy is to include all comments received without change, including any personal information provided, in the public docket, available online at *http://www.regulations.gov,* unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2013–0495. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information you claim as CBI. In addition to one complete version of the comment that includes information claimed as CBI, you must submit a copy of the comment that does not contain the information claimed as CBI for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

The EPA requests that you also submit a separate copy of your comments to the contact person identified below (see **FOR FURTHER INFORMATION CONTACT**). If the comment includes information you consider to be CBI or otherwise protected, you should send a copy of the comment that does not contain the information claimed as CBI or otherwise protected.

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

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available (e.g., CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the EPA Docket Center, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. Visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm* for additional information about the EPA's public docket.

FOR FURTHER INFORMATION CONTACT: Dr. Nick Hutson, Energy Strategies Group, Sector Policies and Programs Division (D243–01), U.S. EPA, Research Triangle Park, NC 27711; telephone number (919) 541–2968, facsimile number (919) 541–5450; email address: *hutson.nick@epa.gov* or Mr. Christian Fellner, Energy Strategies Group, Sector Policies and Programs Division (D243–01), U.S. EPA, Research Triangle Park, NC 27711; telephone number (919) 541–4003, facsimile number (919) 541–5450; email address: *fellner.christian@epa.gov.*

SUPPLEMENTARY INFORMATION: *Outline.* The information presented in this NODA is organized as follows:

I. Does this action apply to me?
II. What are the background and purpose of this NODA?

I. Does this action apply to me?

The entities potentially affected by the determination that is at issue in this NODA are shown in Table 1 below.

TABLE 1—POTENTIALLY AFFECTED ENTITIES [a]

Category	NAICS * code	Examples of potentially affected entities
Industry	221112	Fossil fuel electric power generating units.
Federal Government	[b] 221112	Fossil fuel electric power generating units owned by the federal government.
State/Local Government	[b] 221112	Fossil fuel electric power generating units owned by municipalities.
Tribal Government	921150	Fossil fuel electric power generating units in Indian Country.

* North American Industry Classification System.

[a] Includes NAICS categories for source categories that own and operate electric power generating units (including boilers and stationary combined cycle combustion turbines).

[b] Federal, state or local government-owned and operated establishments are classified according to the activity in which they are engaged.

This table is not intended to be exhaustive but to provide a guide for readers regarding entities likely to be affected by this NODA. To determine whether this NODA affects your facility, company, business, organization, etc., you should examine the applicability criteria in 40 CFR 60.1. If you have questions regarding applicability, consult either the air permitting authority for the entity in question or your EPA regional representative as listed in 40 CFR 60.4 or 40 CFR 63.13 (General Provisions).

II. What are the background and purpose of this NODA?

On January 8, 2014, the EPA published the proposed rule, ''Standards of Performance for Greenhouse Gas Emissions From New Stationary Sources: Electric Utility Generating Units,'' (79 FR 1430) which was issued pursuant to Clean Air Act (CAA) section 111. In the proposed rule, the EPA explains its rationale for emission standards for new fossil fuel-fired boiler and integrated gasification combined cycle (IGCC) electric utility generating units (EGUs). These standards are based on the determination that the best system of emission reduction (BSER) for those sources is partial carbon capture and sequestration (CCS). The EPA today is providing a technical support document (TSD) that addresses the interaction of the determination of BSER in the proposed rule and several provisions in the Energy Policy Act of 2005 (EPAct05), which are described immediately below.

Limitations associated with EPAct05. In providing assistance to fossil fuel-fired electricity generating plants and other facilities that employ advanced technology, EPAct05 included several provisions that limit the EPA's authority to rely on information from those facilities in conducting rulemaking or taking other action under various provisions of the CAA, including section 111. Section 402(i) of the EPAct05, codified at 42 U.S.C. section 15962(i), provides as follows, insofar as is presently relevant, that no technology, or level of emission reduction, *solely* by reason of the use of the technology, or the achievement of the emission reduction, by one or more facilities receiving assistance under EPAct05, shall be considered to be adequately demonstrated for purposes of section 111 of the Clean Air Act.[1]

In addition, internal revenue code (IRC) section 48A(g), codified at 26 USC section 48A(g), provides, insofar as is presently relevant, that no use of technology (or level of emission reduction solely by reason of the use of the technology), and no achievement of any emission reduction by the demonstration of any technology or performance level, by or at one or more facilities with respect to which a credit is allowed under this section, shall be considered to indicate that the technology or performance level is adequately demonstrated for purposes of section 111 of the Clean Air Act.

As explained in the TSD, the EPA's preliminary interpretation of these provisions is that EPA may not rely on information from facilities that have received assistance under EPAct05, including being allowed tax credits under IRC section 48A, as the sole basis for a determination that a particular technology is the best system of emission reduction adequately demonstrated (BSER), but the EPA may rely on information from those facilities in conjunction from other information to support such a determination, or to corroborate an otherwise supported determination. In the TSD, the EPA also explains and solicits comments on other issues of interpretation that arise from the terms of IRC section 48A(g).

2014 Proposal BSER and EPAct05. In the proposed rule, the EPA determined that implementation of partial capture CCS technology is the BSER for new fossil fuel-fired boilers and IGCC units because it fulfills the criteria established under CAA section 111. The EPA's rationale, insofar as is relevant for present purposes, is that partial capture is technically feasible and can be implemented at a reasonable cost. In discussing its rationale, the EPA referenced some facilities that have received financial assistance under the EPAct05, including being allocated tax credits pursuant to IRC section 48A. As explained in the TSD, however, the EPA's rationale does not depend solely upon those projects, and the determination remains adequately supported without any information from facilities that have been allocated the IRC section 48A tax credit.

Thus, the EPA's proposed standards, which are based on its determination that partial capture CCS represents the best system of emission reduction adequately demonstrated, are not beyond the scope of its legal authority. As indicated in the TSD, the EPA solicits comment on all aspects of the interpretation of the provisions in EPAct05, including IRC section 48A(g), that limit the EPA's authority to rely on certain information in rulemaking under CAA section 111.

List of Subjects

40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 71

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

40 CFR Part 98

Environmental protection, Greenhouse gases and monitoring, Reporting and recordkeeping requirements.

Dated: February 5, 2014.

Mary E. Henigin,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2014–03115 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2008–0878; FRL–9906–88–OW]

National Primary Drinking Water Regulations: Minor Corrections to the Revisions to the Total Coliform Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is proposing minor corrections to the final Revisions to the Total Coliform

[1] In addition, EPAct05 Title IV amended the Energy Policy Act of 1992 (42 U.S.C. 13201 et seq.) (EPAct92) by adding the ''Clean Air Coal Program'' to support and promote the production and generation of clean coal-based power, including supporting air pollution control technologies. These provisions included, in EPAct05 § 421(a), a constraint similar to EPAct05 § 402(i). As amended by EPAct05 § 421(a), EPAct92 § 3103(e) (42 U.S.C. 13573(e)) and EPAct92 § 3104(d) (42 U.S.C. 13574(d)), provides, insofar as is presently relevant, under the heading, ''Applicability,'' that no technology, or level of emission reduction, shall be treated as adequately demonstrated for purpose of section 111 of the Clean Air Act solely by reason of the use of such technology, or the achievement of such emission reduction, by one or more facilities receiving assistance under section 3102(a)(1) or (2) of the Energy Policy Act of 1992, as amended (42 U.S.C. 13572(a)(1)).

Rule (RTCR), as authorized under the Safe Drinking Water Act, to correct typographical errors in sections relating to recordkeeping and State primacy requirements, which could affect implementation and enforcement of the RTCR if they were left uncorrected. This proposed action also includes other edits to the final rule language that are intended to improve the understanding of the rule and avoid confusion. This proposed action does not impose new requirements; rather it clarifies what must be included in States' primacy applications related to this rule and the specific records water systems must keep. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is making these minor corrections and edits to the final RTCR as a direct final rule without a prior proposed rule. If we receive no adverse comment, we will not take further action on this proposed rule.

DATES: Written comments must be received by March 28, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2008–0878, by mail to Water Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Sean Conley, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC–4607M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–1781; email address: *conley.sean@epa.gov*. For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 10 a.m. to 4 p.m. Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Why is EPA issuing this proposed rule?

EPA is proposing minor corrections to the final Revisions to the Total Coliform Rule (RTCR) to correct typographical errors in sections relating to recordkeeping and State primacy requirements, which could affect implementation and enforcement of the RTCR if left uncorrected. This proposed action also includes other edits to the final rule language that are intended to improve the understanding of the rule and avoid confusion. This proposed action does not impose new requirements; rather it clarifies what must be included in States' primacy applications related to this rule and the specific records water systems must keep.

II. Regulated Categories and Entities

Entities potentially regulated by the proposed corrections to the final RTCR are all public water systems (PWSs). Regulated categories and entities include the following:

Category	Examples of regulated entities
Industry	Privately-owned community water systems (CWSs), transient non-community water systems (TNCWSs), and non-transient non-community water systems (NTNCWSs).
Federal, State, Tribal, and local governments.	Publicly-owned CWSs, TNCWSs, and NTNCWSs.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities regulated by this action. This table lists the types of entities that EPA is now aware of that could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of ''public water system'' in § 141.2 and the section entitled ''Coverage'' in § 141.3 in title 40 of the Code of Federal Regulations (CFR), and the applicability criteria in § 141.851(b) of the final RTCR. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

C. Copies of This Document and Other Related Information

This document is available for download at *http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/regulation_revisions.cfm.* For other related information, see the docket section of the direct final rule located in the rules section of this **Federal Register**.

D. Minor Corrections to the Revisions to the Total Coliform Rule (RTCR)

Today's proposed rule corrects, as authorized under the Safe Drinking Water Act (SDWA), two typographical errors in the final RTCR (78 FR 10269, February 13, 2013) rule language. First, this proposed action corrects a mistaken cross-reference regarding water system recordkeeping requirements for assessment forms and documentation of corrective actions and sanitary defects. EPA is correcting the cross-reference at § 141.861(b)(1) to correctly provide that assessments, corrective actions and identification of sanitary defects are required under the treatment technique requirements of section 141.859 of the final RTCR. The burden for these recordkeeping requirements was reflected in the Revised Total Coliform Rule and in section 7 of the Economic Analysis (EA) for the Revised Total Coliform Rule (EPA–815–R–12–004).

EPA also discussed these requirements in the preamble to the final RTCR on page 10295. Second, today's proposed rule also corrects the introductory paragraph at § 142.16(q)(2) to correctly indicate that the State's application for primacy must contain a written description of all provisions included in the subsections of the paragraph, (q)(2)(i) through (q)(2)(ix). It was always EPA's intent that primacy applications must contain a written description of all provisions in 142.16(q)(2), but when EPA added subparagraph (q)(2)(ix) to the final rule, EPA neglected to change the numbering in the paragraph (2) lead-in to the list of elements. EPA intended this to be the case, as demonstrated in the preamble to the final RTCR on page 10301. In addition, the burden for this State activity was also included in section 7 of the Economic Analysis (EA) for the RTCR. EPA is not developing a new EA for today's action because the EA for the final RTCR accounts for all costs associated with this rule.

Today's proposed rule also corrects the numbering in § 141.855(a) by adding subparagraph (d)(2) and reserving it, to most simply correct a numbering error that identified a subparagraph (d)(1) without a subsequent (d)(2). Correcting the numbering in this fashion will not interfere with any cross references to subparagraph (d)(1).

Today's proposed rule also includes clarifying revisions to the language regarding primacy applications in § 142.16(q)(2)(ii) to make it more clear in the special primacy requirements section of the RTCR that systems must implement at least one of listed additional criteria to qualify for reduced monitoring. EPA clearly intended this to be the case, as reflected in § 141.854(h)(2) for NCWSs and § 141.855(d) for CWSs, and in the preamble to the final RTCR at pages 10281 and 10282.

Next, the final rule clarifies situations requiring public notification in Appendix A to Subpart Q of Part 141 to list out all of the possible reporting violations under the RTCR that will require Tier 3 public notice. EPA clearly intended this to be the case, as reflected in item (6) in Table 1 to § 141.204 (Violation Categories and Other Situations Requiring a Tier 3 Public Notice), which provides that all reporting and recordkeeping violations under the RTCR require Tier 3 public notice. Also, page 10294 of the preamble to the final RTCR clearly states that Tier 3 PN is required for both monitoring and reporting violations under the RTCR.

Finally, the final rule clarifies the analytical methods table in § 141.852(a)(5) to place the citation ''Standard Methods Online 9223 B–97'' for the Colilert analytical method in the correct column.

These revisions do not change any rule requirements, are consistent with the rule requirements as intended by the Total Coliform Rule/Distribution System Advisory Committee that recommended the revisions to the Total Coliform Rule, and are intended only to clarify requirements and reduce confusion.

II. Additional Supplementary Information

We are publishing a Direct Final Rule to this parallel proposal in the final rule section of today's **Federal Register**. Additional supplementary information is available in the Direct Final Rule, ''National Primary Drinking Water Regulation: Minor Corrections to the Revisions to the Total Coliform Rule.''

Dated: February 10, 2014.

Gina McCarthy,

Administrator.

[FR Doc. 2014–04171 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1460–ANPRM]

RIN 0938–AS05

Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Using Information From Competitive Bidding Programs

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

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: This advance notice of proposed rulemaking (ANPRM) solicits public comments on different methodologies we may consider using with regard to applying information from the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding programs to adjust Medicare fee schedule payment amounts or other Medicare payment amounts for DMEPOS items and services furnished in areas that are not included in these competitive bidding programs. In addition, we are also requesting comments on a different matter regarding ideas for potentially changing the payment methodologies used under the competitive bidding programs for certain durable medical equipment and enteral nutrition.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 28, 2014.

Customer Service Information: Individuals interested in obtaining information from the Centers for Medicare & Medicaid Services concerning current Medicare payment policies may call 1–800–MEDICARE (633–4227) or visit the Centers for Medicare & Medicaid Web site (*http://www.cms.gov*) or (*http://www.medicare.gov*).

ADDRESSES: In commenting, please refer to file code CMS–1460–ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1460–ANPRM, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1460–ANPRM, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT: Anita Greenberg, (410) 786–4601. Karen Jacobs, (410) 786–2173. Christopher Molling, (410) 786–6399. Hafsa Vahora, (410) 786–7899.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments

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

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

I. Background

A. Adjustments to DMEPOS Fee Schedule Amounts

Medicare pays for most DMEPOS furnished after January 1, 1989, pursuant to fee schedule methodologies set forth in sections 1834 and 1842 of the Social Security Act (the Act). Specifically, sections 1834(a)(1)(A) and (B), and 1834(h)(1)(A) and (B) of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. This payment methodology is set forth at 42 CFR part 414, Subpart D of our regulations. Section 1834(h)(1)(A) of the Act governs payment for prosthetic devices and orthotics and prosthetics, while sections 1834(a)(2) through (a)(5) and 1834(a)(7) of the Act set forth separate payment categories of durable medical equipment (DME) and describe how the fee schedule for each of the following categories is established: Inexpensive or other routinely purchased items; Items requiring frequent and substantial servicing; Customized items; Oxygen and oxygen equipment; and Other items of DME. Section 1842(s) of the Act, and 42 CFR part 414, Subpart C of the regulations, govern payment on a fee schedule basis for parenteral and enteral (PEN) nutrients, equipment and supplies.

Section 1847 of the Act establishes a Medicare DMEPOS Competitive Bidding Program (''Competitive Bidding Program''). Under the Competitive Bidding Program, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in competitive bidding areas (CBAs) based on bids submitted by qualified suppliers and accepted by Medicare. For competitively bid items, these new payment amounts, referred to as ''single payment amounts,'' replace the fee schedule payment amounts. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis equal to 80 percent of the applicable single payment amount, less any unmet Part B deductible. The fee schedule methodologies continue to set payment amounts for noncompetitively bid DMEPOS items and services.

For DME covered items furnished or after January 1, 2011, sections 1834(a)(1)(F)(ii) and (iii) of the Act authorizes the Secretary to use (and beginning January 1, 2016, requires use of) payment information under the competitive bidding program to adjust the fee schedule amounts for covered items of DME in all non-competitive bidding areas, and beginning January 1, 2016, continue to make such adjustments to the fee schedule amounts as additional covered items are phased in or information is updated as new contracts are awarded. Similarly, section 1834(h)(1)(H)(ii) of the Act authorizes the Secretary to use payment information under the competitive bidding program to adjust the fee schedule amounts for off-the-shelf (OTS) orthotics in all non-competitive bidding areas beginning January 1, 2011. Finally, section 1842(s)(3)(B) of the Act provides authority to use payment information under the competitive bidding program to adjust payment amounts otherwise applicable for enteral nutrients, supplies, and equipment in areas where competitive bidding programs are not established for these items and services.

Section 1834(a)(1)(G) of the Act requires that the methodology used in applying sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii) of the Act be promulgated through notice and comment rulemaking. Section 1834(a)(1)(G) of the Act also requires that we ''consider the costs of items and services in areas in which such provisions [sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii)] would be applied compared to the payment rates for such items and services in competitive acquisition areas.''

The statute requires that the DMEPOS fee schedule amounts be based on average allowed charges from a base period, increased by annual covered item update factors set forth in the statute. The average allowed charges are average payments made in various areas of the country under the previous reasonable change payment methodology that based Medicare payments on supplier charges. The rules pertaining to the calculation of reasonable charges are located at 42 CFR part 405, Subpart E of our regulations. Under this general methodology, several factors were taken into consideration in determining the reasonable charge for an item. Each supplier's ''customary charge'' for an item, or the 50th percentile of charges for an item over a 12-month period, was one factor used in determining the reasonable charge. The ''prevailing charge'' in a local area or locality, or the 75th percentile of suppliers' customary charges for the item in the locality, was also used in determining the reasonable charge. For parenteral and enteral nutrition (PEN) items and services only, the ''lowest charge level'' (LCL) was also taken into consideration and was based on the 25th percentile of all charges for an item in a locality. For the purpose of calculating the LCL and prevailing charges, a ''locality'' is defined at § 405.505 and ''may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States''. The regulation at § 405.505 further specifies that the locality ''should include a cross section of the population with respect to economic and other characteristics.'' In accordance with regulations at § 405.509, effective for items furnished on or after October 1, 1985, an additional factor, the ''inflation-indexed charge'' or IIC, was added to the factors taken into consideration in determining the reasonable charge for an item. The IIC is equal to the lowest of the customary or prevailing charge from the previous year updated by an inflation adjustment factor was also used in determining the reasonable charge for an item. To summarize, the reasonable charges for each item that were used to calculate the fee schedule amounts are equal to the lower of:

- The supplier's actual charge on the claim;
- The supplier's customary charge for the item;
- The prevailing charge in the locality for the item;
- The LCL in the locality for the item, if applicable; or
- The IIC.

Under the reasonable charge payment methodology, it is understood that suppliers took all of their costs of furnishing various DMEPOS items and services in various localities throughout the nation into account in setting the prices they charges for covered items

and services. Under § 414.104, the fee schedule amounts for enteral nutrients, supplies, and equipment are national fee schedule amounts based on the lesser of the reasonable charge from 1995 or the reasonable charge that would have been used in determining payment for 2002, updated by the covered item update factors. Under § 414.228, the fee schedule amounts for OTS orthotics are regional fee schedule amounts based on the weighted average of the statewide average allowed charges for items furnished from July 1, 1986 through June 30, 1987, updated by the covered item update factors. The regional fee schedule amounts are limited by a national fee schedule ceiling and floor. Under § 414.220 and § 414.222, the fee schedule amounts for inexpensive or routinely purchased DME and DME requiring frequent and substantial servicing are statewide fee schedule amounts based on the average allowed charges for items furnished from July 1, 1986 through June 30, 1987, updated by the covered item update factors, and limited by a national fee schedule ceiling and floor. Under § 414.226, the fee schedule amounts for oxygen and oxygen equipment are statewide fee schedule amounts based on the average allowed charges for items furnished from January 1, 1986 through December 31, 1986, updated by the covered item update factors, and limited by a national fee schedule ceiling and floor. Under § 414.229, the fee schedule amounts for capped rental DME are statewide fee schedule amounts based on the average allowed charges for items furnished from July 1, 1986 through December 31, 1986, updated by the covered item update factors, and limited by a national fee schedule ceiling and floor.

DMEPOS competitive bidding pricing information is collected using current market prices represented by bids submitted by suppliers for furnishing items and services in certain competitive bidding areas (CBAs). In accordance with section 1847(a)(1)(B) and (D) of the Act, during Rounds 1 and 2 of the phase in of the competitive bidding programs, the CBAs have been either entire Metropolitan Statistical Areas (MSAs), MSAs excluding areas with low population density that are not competitive, or, in the case of New York, Los Angeles, and Chicago, MSAs subdivided into two or more CBAs. In accordance with sections 1834(a)(1)(F)(i), 1834(h)(1)(H)(i), and 1842(s)(3)(A) of the Act, the competitive bidding prices, then, replace the fee schedule amounts in those MSAs. Currently, the program is active in 100 MSAs and 109 CBAs. The 109 CBAs where competitive bidding has been phased in include a wide range of different size urban areas and surrounding counties. They include one CBA (Honolulu, HI) that is not within the contiguous Unites States and CBAs that range in population size from approximately 300 thousand to 10 million (see Table 1). There are 7 CBAs with a population of less than 500,000, 41 CBAs with a population of more than 500,000, but less than 1 million, 27 CBAs with a population of more than 1 million, but less than 2 million, 19 CBAs with a population of 2 to 4 million, and 14 CBAs with a population of over 4 million.

TABLE 1—CBA POPULATION SIZE

CBA	Population
Los Angeles County, CA	9,862,049
New York Metro—West Long Island, NY	6,688,637
Dallas-Fort Worth-Arlington, TX	6,447,615
Chicago Metro—Central, IL	6,225,192
Philadelphia-Camden-Wilmington, PA–NJ–DE–MD	5,968,252
Houston-Sugar Land-Baytown, TX	5,867,489
Miami-Fort Lauderdale-Pompano Beach, FL	5,547,051
Washington-Arlington-Alexandria, DC–VA–MD–WV	5,476,241
Atlanta-Sandy Springs-Marietta, GA	5,475,213
Boston-Cambridge-Quincy, MA–NH	4,588,680
Detroit-Warren-Livonia, MI	4,403,437
Phoenix-Mesa-Scottsdale, AZ	4,364,094
San Francisco-Oakland-Fremont, CA	4,317,853
Riverside-San Bernardino-Ontario, CA	4,143,113
Seattle-Tacoma-Bellevue, WA	3,407,848
New York Metro—North New Jersey, NJ	3,390,339
Minneapolis-St. Paul-Bloomington, MN–WI	3,269,814
San Diego-Carlsbad-San Marcos, CA	3,053,793
New York Metro—Bronx, Manhattan, NY	3,026,698
Orange County, CA	3,010,759
New York Metro—South New Jersey, NJ	2,977,504
St. Louis, MO–IL	2,828,990
Tampa-St. Petersburg-Clearwater, FL	2,747,272
Baltimore-Towson, MD	2,690,886
Denver-Aurora, CO	2,552,195
Pittsburgh, PA	2,354,957
Portland-Vancouver-Beaverton, OR–WA	2,241,841
Cincinnati-Middletown, OH–KY–IN	2,171,896
Sacramento—Arden-Arcade—Roseville, CA	2,127,355
Cleveland-Elyria-Mentor, OH	2,091,286
Orlando-Kissimmee, FL	2,082,421
San Antonio, TX	2,072,128
Kansas City, MO–KS	2,067,585
Las Vegas-Paradise, NV	1,902,834
San Jose-Sunnyvale-Santa Clara, CA	1,839,700
Columbus, OH	1,801,848
Charlotte-Gastonia-Concord, NC–SC	1,745,524
Indianapolis-Carmel, IN	1,743,658
Austin-Round Rock, TX	1,705,075

TABLE 1—CBA POPULATION SIZE—Continued

CBA	Population
Virginia Beach-Norfolk-Newport News, VA–NC	1,674,498
Providence-New Bedford-Fall River, RI–MA	1,600,642
Nashville-Davidson—Murfreesboro—Franklin, TN	1,582,264
Milwaukee-Waukesha-West Allis, WI	1,559,667
New York Metro—Suffolk County, NY	1,512,224
Chicago Metro—South, IL	1,446,415
New York Metro—North New York, NY	1,351,732
Jacksonville, FL	1,328,144
Memphis, TN–MS–AR	1,304,926
Louisville/Jefferson County, KY–IN	1,258,577
Richmond, VA	1,238,187
Oklahoma City, OK	1,227,278
Hartford-West Hartford-East Hartford, CT	1,195,998
Chicago Metro—North, IL–WI	1,195,559
New Orleans-Metairie-Kenner, LA	1,189,981
Birmingham-Hoover, AL	1,131,070
Salt Lake City, UT	1,130,293
Raleigh-Cary, NC	1,125,827
Buffalo-Niagara Falls, NY	1,123,804
Rochester, NY	1,035,566
Tucson, AZ	1,020,200
Tulsa, OK	929,015
Fresno, CA	915,267
Honolulu, HI	907,574
Bridgeport-Stamford-Norwalk, CT	901,208
Albuquerque, NM	857,903
Albany-Schenectady-Troy, NY	857,592
Omaha-Council Bluffs, NE–IA	849,517
New Haven-Milford, CT	848,006
Dayton, OH	835,063
Allentown-Bethlehem-Easton, PA–NJ	816,012
Bakersfield, CA	807,407
Worcester, MA	803,701
Oxnard-Thousand Oaks-Ventura, CA	802,983
Baton Rouge, LA	786,947
Grand Rapids-Wyoming, MI	778,009
El Paso, TX	751,296
Columbia, SC	744,730
McAllen-Edinburg-Mission, TX	741,152
Greensboro-High Point, NC	714,765
Chicago Metro—Indiana, IN	702,458
Akron, OH	699,935
Knoxville, TN	699,247
Springfield, MA	698,903
Bradenton-Sarasota-Venice, FL	688,126
Little Rock-North Little Rock-Conway, AR	685,488
Poughkeepsie-Newburgh-Middletown, NY	677,094
Stockton, CA	674,860
Toledo, OH	672,220
Charleston-North Charleston-Summerville, SC	659,191
Syracuse, NY	646,084
Greenville-Mauldin-Easley, SC	639,617
Colorado Springs, CO	626,227
Wichita, KS	612,683
Boise City-Nampa, ID	606,376
Cape Coral-Fort Myers, FL	586,908
Lakeland-Winter Haven, FL	583,403
Youngstown-Warren-Boardman, OH–PA	562,963
Scranton—Wilkes-Barre, PA	549,454
Jackson, MS	540,866
Augusta-Richmond County, GA–SC	539,154
Palm Bay-Melbourne-Titusville, FL	536,357
Chattanooga, TN–GA	524,303
Deltona-Daytona Beach-Ormond Beach, FL	495,890
Visalia-Porterville, CA	429,668
Flint, MI	424,043
Asheville, NC	412,672
Beaumont-Port Arthur, TX	378,477
Ocala, FL	328,547
Huntington-Ashland, WV–KY–OH	285,624

Source: U.S. Census Bureau, Population Division, 2009 Population Estimates.

Under section 1847(a)(1)(D)(iii) of the Act, competitions occurring before 2015 for items and services other than national mail order for diabetic supplies, may not include rural areas or MSAs with a population of less than 250,000. Therefore, at this time, we do not have competitive bidding pricing information from rural areas or smaller MSAs. As required by section 1834(a)(1)(G) of the Act, we must specify by regulation the methodology to be used for adjusting fee schedule amounts using competitive bidding information.

B. Changes to the Payment Methodologies and Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under Competitive Bidding Programs

Section 1847 of the Act provides CMS with flexibility and discretion with regard to the payment rules for items furnished under competitive bidding programs. We are considering proposing new payment rules for DME and enteral nutrients, supplies, and equipment furnished under competitive bidding programs and request public comments on the issue before we decide whether to conduct notice and comment rulemaking. We believe that bundling payment for all items and services associated with furnishing enteral nutrition or DME into one monthly payment based on supplier bids for furnishing all items needed for a month would greatly simplify the program, improve beneficiary access to quality items and services, and contribute to greater savings associated with implementation of the DMEPOS competitive bidding program.

The current Medicare payment rules and payment classes for DME mandated by section 1834(a) of the Act were implemented in 1989, and, depending on the item or payment class the item falls under, generally allow payment on a lump sum purchase basis, a capped rental basis, or a continuous monthly rental basis where the monthly payments are not capped and continue for as long as medical necessity and Part B coverage continues. The continuous monthly rental payment amounts include payment for all necessary maintenance and servicing of the equipment and replacement of all essential accessories, whereas payment on a purchase or capped rental basis results in the need to process and pay separately for numerous items that are not DME but are related to furnishing DME, such as repair of equipment or replacement of supplies and accessories used with patient-owned equipment. In the case of enteral nutrition, there are separate billing codes for categories of nutrients, three different daily supply allowances, feeding tubes, and enteral nutrition infusion pumps and IV poles.

The current payment rules that apply to fee schedule DMEPOS items and competitive bid items were developed in the 1980s to reduce expenditures and prevent prolonged rental payments for certain DME and enteral infusion pumps. However, now that Medicare allowed amounts can be established under the competitive bidding program based on supplier bids to account for the average costs of furnishing all covered items and services, we believe it may be appropriate to modify the Medicare payment structure for certain DME and enteral nutrition under the competitive bidding program by requesting a single bid for furnishing all related items and services needed on a monthly basis (that is, rented equipment, replacement of supplies and accessories, repair or rented equipment, etc.). Bids from suppliers could then be used to establish a monthly payment for the equipment and all related items and services. We believe that capping rentals and paying for purchase of equipment may no longer be necessary to achieve savings for these items and services. Suppliers could bid and be awarded contracts for meeting all of the beneficiary's needs for each month of service, including rental and servicing of necessary equipment as well as the ongoing replacement of supplies and accessories used in conjunction with the equipment and any repairs needed for the equipment. Such an approach could reduce excessive payments for furnishing necessary accessories and items, provided the continuous monthly rental payment amounts were reasonable for all the monthly items and services that would be furnished. In submitting bids under the competitive bidding programs, suppliers would take a number of things into account to develop bids for these monthly items and services, such as the costs of all items and services needed by the beneficiary during each rental month, the typical duration of need by Medicare beneficiaries for the rented items, and the money the supplier saves by replacing inventory less frequently if the title to the equipment remains with the supplier and is not transferred to the beneficiary after the capped rental period. We believe these changes could have a number of positive effects on suppliers. The suppliers would no longer have to worry about counting rental months to determine when they might be losing title to certain items in their inventory. These changes could also benefit patients who would no longer have to arrange for repair of patient-owned equipment or worry about servicing patient-owned equipment for which a manufacturer no longer makes replacement parts available. We believe that suppliers would have an incentive to furnish more durable and dependable equipment to reduce the number of service calls they make. If a beneficiary owns equipment that needs to be serviced, they are responsible for locating a supplier and making arrangements for the servicing, and the beneficiary incurs a separate charge for the service. By contrast, if a beneficiary is renting equipment, and the rented equipment needs to be serviced, the beneficiary would simply call the supplier of the rented equipment and the supplier would be responsible for servicing the equipment at no additional charge. From a program standpoint, the payment rules for capped rental items are complicated and onerous to administer. The program must keep track of separate payment, coverage, medical necessity, and other rules for hundreds of related codes for replacement supplies and accessories used with the base equipment as well as labor and parts associated with repairing patient-owned equipment. In addition, claims processing systems must count rental months and contractors must identify when legitimate breaks in continuous use occur and can result in the start of new capped rental periods. This leads to costly and complicated claims processing systems and edits for processing millions of claims for these items and services.

The current payment rules that allow separate payment for supplies and accessories used with DME in addition to the payment for the DME itself also significantly complicate the competitive bidding process as special grandfathering payment rules must be implemented, item weights and composite bids must be developed, hundreds or thousands of bid amounts must be entered, and, in turn, thousands of bids and bid amounts must be evaluated and screened and single payment amounts established. In the case of beneficiary-owned wheelchairs, the rules regarding when one of the hundreds of accessories or component must be furnished by a contract supplier or non-contract supplier based on whether the base wheelchair is competitively bid or whether the service constitutes a repair of the base wheelchair are extremely complicated. A simple, straightforward payment

system could significantly reduce billing and payment errors.

Under competitive bidding programs established in accordance with section 1847(a) of the Act, we believe CMS has discretion to implement different payment rules for the items and services subject to competitive bidding, including certain DME and enteral nutrition. Suppliers compete for contracts based on bids representing their costs for furnishing the DME item or enteral nutrition. Regardless of whether suppliers compete based on submitting one bid for furnishing, for example, continuous positive airway pressure (CPAP) devices and all related supplies, accessories, and services needed for one month versus separate, piecemeal bids for the various individual items, contracts are offered to the suppliers that meet all program requirements and offer the best value in terms of bids submitted. In addition, contract suppliers are responsible for furnishing what the beneficiary needs and this does not change based on how the items are billed and paid for under Medicare. The supplier costs generally do not change based on the method of payment used. Therefore, competitive bidding provides a means to simplify and streamline complicated payment rules, resulting in a more efficient program.

By simplifying the payment rules for certain DME and enteral nutrition under the Competitive Bidding Program, the process of competitive bidding could be greatly simplified. For example, suppliers could submit one bid that reflects the costs of furnishing the DME and supplies, accessories, and maintenance and servicing costs associated with furnishing the DME. Under competitive bidding, bid limits for the DME could be developed based on average monthly expenditures per beneficiary in an area for the bundle of items and services related to furnishing the DME (for example, CPAP device rental, masks, tubing, humidifier, maintenance and servicing). Similarly, bid limits for enteral nutrition could be developed based on average monthly expenditures per beneficiary in an area for the bundle of items and services related to furnishing enteral nutrition (nutrients, supplies, rental of infusion pumps and IV poles, and maintenance and servicing of equipment). These are some possibilities we are exploring with regard to modifications that could be made to current payment rules and methodologies under the CBP in future rulemaking. Whether we would proceed with proposing this would depend on several factors, including issues such as administrative burden and feasibility, as well as other potential issues raised in the public comments we receive.

II. Questions for Generating Public Comments

A. Methodology for Adjusting Medicare Payment Amounts for DMEPOS Items and Services Based on Information From Competitive Bidding Programs

We are aware that there continues to be a range of aspects to consider in the development of the methodology used to adjust fee schedule amounts for DMEPOS using information from the competitive bidding programs. Again, we are required by section 1834(a)(1)(G) of the Act, to specify by regulation the methodology to be used for adjusting fee schedule amounts using competitive bidding information. However, prior to proposing the methodology, we are soliciting public comments on a variety of topics for CMS to consider. We are interested in receiving comments on several aspects that we would consider in developing a methodology to adjust DMEPOS fee schedule amounts or other payment amounts in non-competitive areas based on DMEPOS competitive bidding payment information. We are soliciting comments on the following list of questions to assist us in developing potential proposals regarding the methodology for adjusting Medicare payment amounts for DMEPOS items and services based on information from competitive bidding programs.

- Do the costs of furnishing various DMEPOS items and services vary based on the geographic area in which they are furnished? If so, how should the bidding information obtained from programs established in different regions of the nation be grouped together for the purpose of adjusting current Medicare payment amounts? Should bidding information from programs established in certain regions of the country be used to adjust the payment amounts that currently apply to those regions? Are there certain areas of the country that have unique costs and how should those costs be considered? Is there valid and reliable information that can be used to measure the relative costs of furnishing items and services in these unique areas?
- Do the costs of furnishing various DMEPOS items and services vary based on the size of the market served in terms of population and/or distance covered or other logistical or demographic reasons? Section 1847(a)(1)(D)(iii) of the Act prohibits establishing competitive bidding programs in MSAs with a population of less than 250,000 or in areas outside MSAs prior to 2015. Given the mandate to use information on the payment determined under competitive bidding programs to adjust payment amounts in areas that are not competitive bidding areas by no later than January 1, 2016, what alternative information, if any, should we rely on to determine the relative costs of furnishing items and services in these areas compared to areas where competitive bidding programs have already been implemented?
- How should any future adjustments or payment methodology treat payment amounts for items that have not been included in all competitive bidding programs (for example, items such as transcutaneous electrical nerve stimulation (TENS) devices that have only been phased into the nine Round 1 areas thus far)?
- Should competitive bidding programs be established in all areas of the country for a few high volume items in order to gather information regarding the costs of furnishing DMEPOS items, in general, in different areas of the country (for example, rural areas as well as urban areas)?
- For payment adjustments or competitive bidding programs in rural areas, what factors should be used in determining a competitive service area in terms of Medicare revenue available and logistical costs of serving the area? Are there ways to determine which rural counties should be served by which suppliers?
- What additional factors should be considered and why?

B. Changes to the Payment Methodologies and Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under Competitive Bidding Programs

We are requesting comments on testing or phasing in bundled payments under competitive bidding programs whereby suppliers would submit one bundled bid for the delivery of all enteral nutrients, supplies, and equipment needed for one month by a beneficiary as well as one bundled bid for furnishing certain DME, including all related supplies, accessories, and services on a monthly basis. Under such an approach, monthly rental payments for DME or enteral nutrition equipment would no longer reach a cap, while separate payment for supplies, accessories, enteral nutrients, or maintenance and servicing would no longer be made. Suppliers would retain title to all equipment regardless of length of need and beneficiaries would be able to switch from supplier to supplier on a monthly basis. The monthly payments for DME and enteral

nutrition would continue for as long as medical necessity and Part B coverage continues and the bid limits would be based on the average monthly costs per beneficiary for the bundle of items and services. We are soliciting comments on the following list of questions regarding proposals we may make to change the payment rules and other rules for DME and enteral nutrition under the DMEPOS competitive bidding program.

- Are lump sum purchases and capped rental payment rules for DME and enteral nutrition equipment that were implemented to prevent prolonged rental payments still needed now that monthly payment amounts can be established under competitive bidding programs for furnishing everything the beneficiary needs each month related to the covered DME item or enteral nutrition?
- Are there reasons why beneficiaries need to own expensive DME or enteral nutrition equipment rather than use such equipment as needed on a continuous monthly basis?
- Would there be any negative impacts associated with continuous bundled monthly payments for enteral nutrients, supplies, and equipment or for certain DME? If so, please explain.
- Certain DME items such as speech generating devices and specialized wheelchairs may be adjusted or personalized to address individual patient needs. Would payment on a bundled, continuous rental basis adversely impact access to these items and services? If so, please provide a detailed explanation regarding how this method of payment would create a negative impact on access to these items and services or other items and services currently subject to competitive bidding.
- If payment on a capped rental, rent-to-own basis or lump sum purchase basis is maintained for certain items under the competitive bidding program, should a requirement be added to the regulations specifying that the supplier that transfers title to the equipment to the beneficiary is responsible for all maintenance and servicing of the beneficiary-owned equipment for the remainder of the equipment's reasonable useful lifetime with no additional payment for these services? The cost of such a mandatory supplier warranty would be factored into the bids submitted by the suppliers and the payment amounts established based on the bids for the items. If such a requirement was established, should the term maintenance and servicing be defined to include all necessary maintenance, servicing and repairs that are currently paid for separately under the Medicare program in addition to any additional adjustments or personalization of the equipment that may be needed once title transfers to the patient? We believe these requirements may be necessary to safeguard the beneficiary and access to necessary services related to beneficiary-owned DME.
- Would payment on a bundled, continuous rental basis for certain items adversely impact the beneficiary's ability to direct their own care, follow a plan of care outlined by a physician, nurse practitioner or other medical provider (for example, occupational, physical or speech therapist), or provide for appropriate care transitions? If so, please explain.
- What are the advantages or disadvantages for beneficiaries and suppliers of bundled bidding and payments for enteral nutrients, supplies, and equipment or DME?
- Should competitive bidding programs utilizing bundled payments be established throughout the entire United States so that all beneficiaries are included under programs where suppliers have an obligation to furnish covered items and all related items and services?
- Is a continuous bundled monthly payment used by commercial payers or State Medicaid programs for enteral nutrients, supplies, and DME and do these approaches inform this potential new payment arrangement for Medicare.

Dated: January 31, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 4, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2014–04031 Filed 2–24–14; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

6 CFR Chapter I

8 CFR Chapter I

19 CFR Chapter I

33 CFR Chapter I

44 CFR Chapter I

46 CFR Chapters I and III

49 CFR Chapter XII

[Docket No. DHS–2014–0006]

Retrospective Review of Existing Regulations; Request for Public Input

AGENCY: Office of the General Counsel, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Department of Homeland Security (Department or DHS) is seeking comments from the public on specific existing significant DHS rules that the Department should consider as candidates for modification, streamlining, expansion, or repeal. These efforts will help DHS ensure that its regulations contain necessary, properly tailored, and up-to-date requirements that effectively achieve regulatory objectives without imposing unwarranted costs.

DHS is seeking this input pursuant to the process identified in DHS's Final Plan for the Retrospective Review of Existing Regulations. According to the Final Plan, DHS will initiate its retrospective review process, on a three-year cycle, by seeking input from the public. The most helpful input will identify specific regulations and include actionable data supporting the nomination of specific regulations for retrospective review.

DATES: Written comments are requested on or before March 28, 2014. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may submit comments, identified by docket number DHS–2014–0006, through the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Charlotte Skey, Senior Regulatory Economist, Office of the General Counsel, U.S. Department of Homeland Security. Email: *Regulatory.Review@dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to comment on this notice by submitting written data, views, or arguments using the method identified in the **ADDRESSES** section.

Instructions: All submissions must include the agency name and docket number for this notice. All comments received will be posted without change to *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov.*

II. Background

On January 18, 2011, the President issued Executive Order 13563, ''Improving Regulation and Regulatory Review,'' to ensure that Federal regulations seek more affordable, less intrusive means to achieve policy goals and that agencies give careful consideration to the benefits and costs of those regulations. 76 FR 3821. The Executive Order required each Executive Branch agency to develop a preliminary plan to periodically review its existing regulations to determine whether any regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving its regulatory objectives.

DHS's approach to conducting retrospective review focuses on public openness and transparency and on the critical role of public input in conducting retrospective review. To that end, DHS published a notice and request for comments in the **Federal Register** on March 14, 2011. 76 FR 13526. In that notice, DHS solicited public input on how DHS should structure its retrospective review and which DHS rules would benefit from retrospective review. On June 6, 2011, DHS published a notice of availability; request for comments announcing the availability and seeking comment on its Preliminary Plan for the Retrospective Review of Existing Regulations. 76 FR 32331. DHS considered this public input as it developed a Final Plan.

On August 22, 2011, DHS issued its Final Plan for the Retrospective Review of Existing Regulations (Final Plan or DHS Final Plan). The DHS Final Plan is available online at *http://www.dhs.gov/xlibrary/assets/dhs-ogc-final-retrospective-review-plan-8-22-11-final.pdf.* The Final Plan established a process for identifying regulations that may be obsolete, unnecessary, unjustified, excessively burdensome, or counterproductive. Under the Final Plan, DHS (and/or a DHS component) will publish a notice in the **Federal Register** every three years seeking public input regarding the regulations that should be subject to retrospective review. The previous **Federal Register** notice from DHS seeking such public input was published in 2011. 76 FR 13526. The notice published today in the **Federal Register** requesting nominations for additional regulations that should be subject to retrospective review fulfills the DHS commitment to seek public input via the **Federal Register** on a three-year cycle.

It is important to note that DHS continually evaluates its regulatory program for rules that are candidates for retrospective review. DHS does so through legally mandated retrospective review requirements (e.g., Unified Agenda reviews and reviews under section 610 of the Regulatory Flexibility Act) and through other informal and long-established mechanisms (e.g., use of Advisory Councils, feedback from DHS field personnel, input from internal working groups, and outreach to regulated entities). This **Federal Register** notice supplements these existing extensive DHS retrospective review efforts.[1]

II. DHS's Regulatory Responsibility

DHS's mission is to ensure a homeland that is safe, secure, and resilient against terrorism and other hazards. The Department carries out its mission through the Office of the Secretary and 28 components, including the following seven operational components: U.S. Citizenship and Immigration Services, U.S. Coast Guard, U.S. Customs and Border Protection, Federal Emergency Management Agency, U.S. Immigration and Customs Enforcement, U.S. Secret Service, and Transportation Security Administration.

Our mission gives us five main areas of responsibility: (1) Prevent terrorism and enhance security; (2) secure and manage our borders; (3) enforce and administer our immigration laws; (4) safeguard and secure cyberspace; and (5) ensure resilience to disasters. To further these areas, DHS has responsibility for a broad range of regulations. For example, to secure and manage our borders, DHS regulates people and goods entering and exiting the United States. DHS, to combat terrorism, regulates aviation security, high-risk chemical facilities, and infrastructure protection. DHS also issues regulations to administer immigration and citizenship benefits as well as regulations covering maritime safety and environmental protection. Finally, DHS promulgates a wide range of regulations concerning disaster preparedness, response, and recovery.

III. Request for Input

A. Importance of Public Feedback

A central tenet of the DHS Final Plan is the critical and essential role of public input in driving and focusing DHS retrospective review. Because the impacts and effects of a rule tend to be widely dispersed in society, members of the public—especially the regulated entities of our rulemakings—are likely to have useful information, data, and perspectives on the benefits and burdens of our existing regulations. Given this importance of public input, the primary factor for rule section in DHS retrospective review is public feedback.

B. Maximizing the Value of Public Feedback

This notice contains a list of questions, the answers to which will assist DHS in identifying those regulations that may benefit from DHS retrospective review. DHS encourages public comment on these questions and seeks any other data commenters believe are relevant to DHS's retrospective review efforts. The DHS Final Plan provides instruction on the type of feedback that is most useful to the Department:

> DHS will afford significantly greater weight to feedback that identifies *specific regulations,* includes *actionable data,* or provides *viable alternatives* that meet statutory obligations and regulatory objectives. Feedback that simply states that a stakeholder feels strongly that DHS should change a regulation, but does not contain specific information on how the proposed change would impact the costs and benefits of the regulation, is much less useful to DHS. DHS is looking for new information and new economic data to support any proposed changes. (emphasis added)

We highlight a few of those points here, noting that comments that will be most useful to DHS are those that are guided by the principles below. Commenters should consider these principles as they answer and respond to the questions in this notice.

- Commenters should identify, with specificity, the regulation at issue, providing the Code of Federal Regulation (CFR) cite where available.
- Commenters should provide, in as much detail as possible, an explanation why a regulation should be modified,

[1] Twice a year, DHS posts a progress report on the DHS Web site; the report provides the status of DHS regulations currently under retrospective review. The most recent progress report was published in July 2013 and is available on the DHS Web site at *http://www.dhs.gov/latest-progress.*

streamlined, expanded, or repealed, as well as specific suggestions of ways the Department can better achieve its regulatory objectives.

• Commenters should provide specific data that document the costs, burdens, and benefits of existing requirements. Commenters might also address how DHS can best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations and whether there are existing sources of data that DHS can use to evaluate the post-promulgation effects of its regulations over time.

• Particularly where comments relate to a rule's costs or benefits, comments will be most useful if there are data and experience under the rule available to ascertain the rule's actual impact. For that reason, we encourage the public to emphasize those rules that have been in effect for a sufficient amount of time to warrant a fair evaluation.

• Comments that rehash debates over recently issued rules will be less useful.

C. List of Questions for Commenters

The below nonexhaustive list of questions is meant to assist members of the public in the formulation of comments and is not intended to restrict the issues that commenters may address:

(1) Are there regulations that simply make no sense or have become unnecessary, ineffective, or ill advised and, if so, what are they? Are there regulations that can simply be repealed without impairing the Department's regulatory programs and, if so, what are they?

(2) Are there regulations that have become outdated and, if so, how can they be modernized to better accomplish their regulatory objectives?

(3) Are there regulations that are still necessary, but have not operated as well as expected such that a modified, stronger, or slightly different approach is justified?

(4) Does the Department currently collect information that it does not need or effectively use to achieve regulatory objectives?

(5) Are there regulations that are unnecessarily complicated or could be streamlined to achieve regulatory objectives in more efficient ways? If so, how can they be streamlined and/or made less complicated?

(6) Are there regulations that have been overtaken by technological developments? Can new technologies be leveraged to modify, streamline, or do away with existing regulatory requirements?

(7) Are there any Departmental regulations that are not tailored to impose the least burden on society, consistent with achieving the regulatory objectives?

(8) How can the Department best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations? Are there existing sources of data the Department can use to evaluate the post-promulgation effects of regulations over time?

(9) Are there regulations that are working well that can be expanded or used as a model to fill gaps in other DHS regulatory programs?

(10) Are there any regulations that create difficulty because of duplication, overlap, or inconsistency of requirements?

The Department notes that this notice is issued solely for information and program planning purposes. Responses to this notice do not bind DHS to any further actions related to the response.

Christina E. McDonald,

Associate General Counsel for Regulatory Affairs.

[FR Doc. 2014–04116 Filed 2–25–14; 8:45 am]

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Notices

Federal Register

Vol. 79, No. 38

Wednesday, February 26, 2014

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

Submission for OMB Review; Comment Request

February 20, 2014.

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 regarding (a) 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; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, 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. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utility Service

Title: High Energy Cost Grants and State Bulk Fuel Revolving Grant Programs.

OMB Control Number: 0572–0136.

Summary of Collection: The Rural Electrification Act of 1936 (RE Act) (7 U.S.C. 901 et seq.) was amended in November 2000 to create new grant and loan authority to assist rural communities with extremely high energy costs (Pub. L. 106–472). This amendment gives authorization to Rural Utilities Service (RUS) to provide competitive grants for energy generation, transmission, or distribution facilities serving communities in which the national average is at least 275% for residential expenditure for home energy. All applicants are required to submit a project proposal containing the elements in the prescribed format.

Need and Use of the Information: USDA will collect information from applicants to confirm that the eligibility requirements and the proposals are consistent with the purposes set forth in the statute. Various forms and progress reports are used to monitor compliance with grant agreements, track expenditures of Federal funds and measure the success of the program. Without collecting the listed information, USDA will not be assured that the projects and communities served meet the statutory requirements for eligibility or that the proposed projects will deliver the intended benefits.

Description of Respondents: Not-for-profit institutions; Business or other for-profit; and State, Local or Tribal Government.

Number of Respondents: 100.

Frequency of Responses: Recordkeeping: Reporting: On occasion.

Total Burden Hours: 1,052.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–04181 Filed 2–25–14; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Forest Service

Assessment Report of Ecological/Social/Economic Sustainability, Conditions, and Trends for the Tonto National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice of initiating the assessment phase of the Tonto National Forest land management plan revision.

SUMMARY: The Tonto National Forest, located in Arizona, is initiating the forest planning process pursuant to the 2012 Forest Planning Rule. This process results in a Forest Land Management Plan which describes the strategic direction for management of forest resources for the next ten to fifteen years on the Tonto National Forest. The first phase of the process, the assessment phase, has begun and interested parties have been invited to contribute in the development of the assessment (36 CFR 219.6). The Forest hosted a series of listening sessions with key stakeholders in January 2014, and will be hosting workshops in March 2014. Additional information on public participation opportunities will be available on the project Web site. The trends and conditions identified in the assessment will help in identifying the need for change, in the development of plan components.

DATES: A draft of the assessment report for the Tonto National Forest is expected to be completed by early to mid-winter 2014/2015 and will be posted on the following Web site at *www.fs.usda.gov/goto/TontoForestPlanRevision*.

From January 2014 through November 2014, the public is invited to engage in a collaborative process to identify relevant information and local knowledge to be considered for the assessment. The Forest will then initiate procedures pursuant to the NEPA and prepare a forest plan revision. The Forest will again be inviting the public to help us identify the appropriate plan components that will become a proposed action for the land management plan revision.

ADDRESSES: Written comments or questions concerning this notice should be addressed to Tonto National Forest, Attn.: Plan Revision, 2324 E. McDowell Road, Phoenix, AZ 85006.

FOR FURTHER INFORMATION CONTACT: Ken Born, Forest Planner, 602–225–5280. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 5 a.m. and 5 p.m., Pacific Time, Monday through Friday. More information on the planning process can also be found on the Tonto National Forest Web site at *www.fs.usda.gov/goto/TontoForestPlanRevision.*

SUPPLEMENTARY INFORMATION: The National Forest Management Act (NFMA) of 1976 requires that every National Forest System (NFS) unit develop a land management plan. On April 9, 2012, the Forest Service finalized its land management planning rule (2012 Planning Rule), which provides broad programmatic direction to National Forests and National Grasslands for developing and implementing their land management plans. Forest plans describe the strategic direction for management of forest resources for ten to fifteen years, and are adaptive and amendable as conditions change over time.

Under the 2012 Planning Rule, the assessment of ecological, social, and economic trends and conditions is the first stage of the planning process. The second stage is a development and decision process guided, in part, by the National Environment Policy Act (NEPA) and includes the preparation of a draft environmental impact statement and revised Forest Plan for public review and comment, and the preparation of the final environmental impact statement and revised Forest Plan. The third stage of the process is monitoring and feedback, which is ongoing over the life of the revised forest plans.

With this notice, the agency invites other governments, non-governmental parties, and the public to contribute to the development of the assessment report. The assessment will rapidly evaluate the sustainability of existing ecological, economic, and social conditions and trends within the context of the broader landscape. It will help inform the planning process through the use of Best Available Scientific Information, while also taking into account other forms of knowledge, such as local information, national perspectives, and native knowledge. Lastly, the assessment will help identify the need to change the existing 1985 plan. Collaboration as part of the assessment phase supports the development of relationships of key stakeholders throughout the plan revision process, and is an essential step to understanding current conditions, available data, and feedback needed to support a strategic, efficient planning process.

As public meetings, other opportunities for public engagement, and public review and comment opportunities are identified to assist with the development of the forest plan revision, public announcements will be made, notifications will be posted on the Forest's Web site at *www.fs.usda.gov/goto/TontoForestPlanRevision* and information will be sent out to the Forest's mailing list. If anyone is interested in being on the Forest's mailing list to receive these notifications, please contact Ken Born, Forest Planner, at the mailing address identified above, by sending an email to *tontoplan@fs.fed.us.*

Responsible Official

The responsible official for the revision of the land management plan for the Tonto National Forest is Neil Bosworth, Forest Supervisor, Tonto National Forest, 2324 E. McDowell Road, Phoenix, AZ 85006.

Dated: February 18, 2014.

Neil J. Bosworth,

Forest Supervisor.

[FR Doc. 2014–04006 Filed 2–25–14; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

New Mexico Collaborative Forest Restoration Program Technical Advisory Panel

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The New Mexico Collaborative Forest Restoration Program Technical Advisory Panel (Panel) will meet in Albuquerque, New Mexico. The Panel is established consistent with the Federal Advisory Committee Act of 1972 (5 U.S.C. App II) and the Community Forest Restoration Act (Title VI, Pub. L. 106–393). Additional information concerning the Panel can be found by visiting the Panel's Web site at: *http://www.fs.usda.gov/goto/r3/cfrp.*

DATES: The meeting will be held April 7–11, 2014, beginning at 10:00 a.m. on Monday, April 7, 2014 and ending at approximately 4:00 p.m. on Friday, April 11, 2014.

ADDRESSES: The meeting will be held at the Hyatt Place Albuquerque/Uptown, 6901 Arvada Avenue NE., Albuquerque, NM 87110, (505) 872–9000. Written comments should be sent to Walter Dunn, Cooperative and International Forestry, USDA Forest Service, 333 Broadway SE., Albuquerque, NM 87102. Comments may also be sent via email to *wdunn@fs.fed.us,* or via facsimile at (505) 842–3165.

All comments, including names and addresses, when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Cooperative and International Forestry Office, USDA Forest Service, 333 Broadway SE., Albuquerque, NM 87102. Please call ahead at (505) 842–3425 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Walter Dunn, Designated Federal Official, (505) 842–3425, Cooperative and International Forestry, USDA Forest Service, 333 Broadway SE., Albuquerque, NM 87102.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide recommendations to the Secretary of Agriculture on which applications submitted in response to the Collaborative Forest Restoration Program Request For Applications best meet the program objectives.

The meeting is open to the public. Panel discussion is limited to Panel members and Forest Service staff. Project proponents may respond to questions of clarification from Panel members or Forest Service staff. However, the agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by March 28, 2014 to be scheduled on the agenda. Anyone who would like to bring Collaborative Forest Restoration Program grant application review related matters to the attention of the Panel may file written statements with the Panel staff before or after each day of the meeting. A summary of the meeting will be posted on the Web site listed above within 45 days after the meeting.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by

contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: February 19, 2014.

Gilbert Zepeda,

Deputy Regional Forester.

[FR Doc. 2014–04147 Filed 2–25–14; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

White Pine-Nye Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The White Pine-Nye Resource Advisory Committee (RAC) will meet in Eureka, Nevada. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to review and make recommendations on project proposals.

DATES: The meeting will be held Thursday, March 27, 2014, at 9:00 a.m. (PST).

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Eureka County Annex, 701 S. Main Street, Eureka, Nevada.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Tonopah Ranger District Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Linda Bernardi, RAC Coordinator, by phone at 775–482–6286 or via email at *lebernardi@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday. Please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accomodation for access to the facility or procedings by contacting the person listed above.

SUPPLEMENTARY INFORMATION: Additional RAC information, including the meeting agenda and the meeting summary/minutes can be found at the following Web site: *https://fsplaces.fs.fed.us/fsfiles/unit/wo/secure_rural_schools.nsf.* The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by March 19, 2014 to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Linda Bernardi, RAC Coordinator, Tonopah Ranger District, P.O. Box 3940, Tonopah, Nevada 89049; or by email to *lebernardi@fs.fed.us,* or via facsimile to 775–482–3053.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: February 19, 2014

William A. Dunkelberger,

Forest Supervisor.

[FR Doc. 2014–04151 Filed 2–25–14; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–18–2014]

Foreign-Trade Zone (FTZ) 247—Erie, Pennsylvania; Notification of Proposed Production Activity, GE Transportation, (Locomotives, Off-Highway Vehicles and Motors/Engines), Lawrence Park and Grove City, Pennsylvania

GE Transportation submitted a notification of proposed production activity to the FTZ Board for its facilities in Lawrence Park and Grove City, Pennsylvania within Subzones 247A and 247B. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on February 14, 2014.

GE Transportation already has authority to produce locomotives; off-highway vehicle wheels, inverters and brake systems; components, spare parts and subassemblies for locomotives and off-highway vehicles; drill equipment; marine equipment; stationary equipment; diesel locomotive engines; engine turbo chargers; power assemblies; other engine assemblies; and, engine components and spare parts within Subzones 247A and 247B. The current request would add finished products and foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/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 GE Transportation from customs duty payments on the foreign status materials/components used in export production. On its domestic sales, GE Transportation would be able to choose the duty rates during customs entry procedures that apply to the finished products in the existing scope of authority as well as: Tank assemblies; tank reservoirs; waste receptacles; head hitters; wiper arm mounting assemblies; wiper blades; wiper arms; blades; brass heater cylinders; air horn tubes; high pressure nozzles; wiper connecting rods; heating elements; photodiscs; armatures; ringer bells; wiper arm bases; and, motors (duty rate ranges from duty-free to 4%) for the foreign status materials/components noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The materials/components sourced from abroad include: Salt; sodium bentonite powder; plaster of Paris; concrete mix; petroleum-based engine oil; lube oil; lubricating oil; petroleum jelly paste; corrosive preventative solvent; nitrogen cartridges; compressed nitrogen; carbon dioxide tire suppression; magnesium hydroxide; aluminum oxide; beta alumina powder; boehmite—aluminum hydroxide; sodium fluoride; aluminum chloride; sodium iodide; ferrous sulphide; sodium carbonate powder; saline solution; lithium hydroxide; bidistilled water; vinyl toluene; solvent and

thinners; paint solvent; acetone; polycarbonate acid; first aid kits; preps based on carbon black; silica/borsilicate powder; acrylic and vinyl paints and varnishes; non-aqueous paints and varnishes; mastics; caulking compounds; rubber glaziers' putty; writing inks and other inks; organic composite solvents; cleaning fluids; bearing oil lubricants; contact grease; petroleum lubricants; lithium soap grease; molytec silicone lubricants; synthetic bearing grease; polyethylene glycol 400; adhesives; sealants; neoprene rubber adhesive sealants; epoxy adhesives; epoxy resins; signaling flares; red flares; brazing flux; solder flux; antox pickling paste; rust preventative lubricants; rust inhibiting compounds; monoammonium phosphates; fire extinguishing chemical agents; liquid tempilaq trichloroethelen; heavy-duty degreasers; engine cleaners; polyurethane activator catalysts; activators; refractory glue; sodium hexametaphosphate; liquid polymers; epoxy kits; epoxy; emersion epoxy; fiberglass tape; varnish; silicone fluid; liquid silicone; plastic tubing; PVC, plastic and plastic-threaded pipes; phenlolic tubes; thermoset plastic tubes; hose assemblies; hoses; tubes; Teflon® hoses; heat shrink tube sleeves; polyolefin heat shrink tubes; nylon tubes; flexible plastic hoses; nylon plastic pipes; vinyl floor mats; floor mats; console mats; non-skid mats; 3M™ walkway tape; Teflon® strips; seal plastic; insulators; indicator plates; plastic non-adhesive labels; lexan plastic lens strips; reverser sliders; tapes; cloth and treated glass cloth; thermal insulation; polyurethane foam; polyfoam insulation; plastic toilet seats; shipping containers; plastic shipping containers plastic canisters; plastic bags; plastic trays; light palettes; polyethylene inserts; scour pads; toilet dispenser covers; zinc-plated door handles; paper sheet holders; crew pack holders; operator cab card holders; plastic knobs; neoprene raw materials; rubber tape; NBR/PVC thermal insulation; neoprene protection blankets; rubber insulation strips; rubber hoses; radiator hoses; coolant hoses; Dacron®-reinforced rubber hoses; sand hoses; hoses; water hoses; insul ducts; V-belts; rubber belts; cog belts; rubber V-belts; rubber matting; floor cab material; window weather seals; rubber gaskets; plastic trunks and suitcases; aluminum cases; steel tool chests; steel tool boxes; tool carrying cases; veneer panels; blocks; wood crates; shipping crates; wood shipping skids; wooden crates; locomotive cribbing; wood studs; locomotive engine diesel covers; wood lead clamps; wood stop blocks; wood trays; battery liner blocks; corprene oil gaskets; gaskets; fuel sight gaskets; bearing housing gaskets; cork gaskets; paper towels; paper cloth; thermal paper rolls; cellulose towels; disposable towels; kim tech wipes; corrugated cardboard boxes; paperboard boxes; cardboard boxes; labels; paper gaskets; paper catalogs; paper documents; user manuals; paper instruction sheets; paperback books; hardcover books; photocopies; engineering drawings; wiring schematics; plastic decals; business cards; locotrol system catalogs; catalogs; twine; felt wicks; paper insulation; ropes; safety nets; polypropylene nets; cotton cording; insulating fitting; duct tape; flexible duct hoses; neoprene polyester fabric hoses; rayon V-belts; curtains; sacks and bags for packing; web slings; protective pads; cloth bags; hard hats; stones; abrasive cleaning discs; grinding wheel stones; emery discs; resurfacing stones; grinders; brush seaters; abrasive paper; polishing paper sets; sequin epoxy resin paper; alumina fiber insulation modules; polycrystalline alumina fiber mats; locomotive insulation stone wool; insulating wool; inorganic silicates thermal insulation; air brake washers; exhaust gas flange gaskets; intumescent fire seals; graphite gaskets; grafoil gaskets; TCB alumina spacers; beta alumina space tubes; alumina rods; beta alumina tubes; pressing ceramic rings; ceramic gaskets; ceramic sheets; glass tubes; glassing; sliding glass; mirrors; reflective mirrors; inspection mirrors; indicator lamp glass lenses; glass tubes; frosted light glass; lenses; glass lenses; converse lenses; glass beads; fiberglass cords; fiberglass insulation material; glastic sheets; fiberglass insulation; heat blankets; insulation strips; fiberglass cloth; glass tape; fiberglass nuts and rods; brazing pieces; ballasts; iron powder; alloy steel raw plates; raw steel plates; raw steel sheets; steel; steel wear plates; steel plates; steel rods; threaded bars; round steel bars; wires; channel steel; steel angles; wire steel bindings; stainless steel sheets; locking wires; locking wire steel wires; steel wires; carbon steel sheets; round bars; mounting angles; steel angles; clamps; steel rail clamps; stainless steel tubes and pipes; steel alloy pipes; cold drawn steel pipes; steel tubes; pipes; oil pipes; rectangular steel pipes; spacer threaded steel pipes; steel flanges; stainless steel sleeves and pipe fittings; bridge steel foundation; structural steel; steel cantilever masts; reservoirs; main air reservoirs; locomotive tanks; retaining wires; steel mesh screens; journals; connecting links; handbrake chain assemblies; chain steel links; steel staples; wood screws; J-hook screws; self-tapping screws; steel rivets; stainless steel pins; springs; hot air blowers; steel waste receptacles; stainless steel sinks; folding locomotive sinks; toilet seat arrangements; toilet water tanks; followers; steel shackles; forged steel rings; steel handrail clamps; end rings; steel binding wires; copper wire, bars and raw materials; brass coils; disks; copper foil tape and tubes; rapid unloader copper tubes; copper tubing; fitting nipples; copper pins; escutcheon brass pins; brass rivets; brass toggle bolts; copper retaining rings; adjustable screws; brass machine screws; brass locking nits; nuts; copper studs; brass studs; double ended screws; cartridges; bronze rings; threaded copper inserts; chains; nickel granules; nickel powder; nickel alloy wire and strips; aluminum powder, flakes, pipes and angles; mute aluminum panels; aluminum plates and base plates; damping sheets; electric marker tape; aluminum doors, door assemblies, roof panels and floor panels; aluminum casks, drums, cans and rivets; pop rivets; lead wire, stamps and seals; zinc elbows and couplings; hand spring brakes; hole saws; aluminum slot files; slip joint pliers; tool sets; needle nose pliers; pipe cutters; wrenches; adapters; wrench sets; nut drives; ratchet sets; sockets; hammers; screwdrivers; piston holding tools; caulking gun nozzles; hand brake tool kits; gear puller sets; tool sets; hand tool sets; tool bags; dies; die sets; drill taps, inserts and bits; cobalt drill bit sets; drill driver bits; carbide end mills; cutter end mills; file segments; keys; steel castors; pneumatic cylinder raising cylinder assemblies; gas spring cylinders; dashpots; staples; signaling bells; locomotive clappers; air horn bells; clevis; lube oil inlet covers; outer steel seals; brazing heads; brazing head holders; piping diesel fuel lines; intake rotators; main governors; cylinder heads; camshaft covers; strongback castings; cylinder jackets; air intake manifolds; diesel engine orifices; rotators; vibration dampers; oil pans; pipe assemblies; piston crowns; diffusers; water discharge headers; exhaust manifolds; piston skirts; manifold blocks; piston pins; alignment rings; push rods; crankcase door assemblies; power assemblies; art rod assemblies; valve seats; rocker arm assemblies; high pressure fuel lines; diesel heads; rocker assemblies; strongbacks; crankcases; cylinder liners; engine fuel lines; fuel header assemblies; frame assemblies; nozzle rings; fire suppression system gas charge motors; cylinders; hydraulic motor

assemblies; pneumatic actuators; air brake cylinders; hydraulic pumps; lube oil engine measuring pumps; pumps; vacuum pumps; air compressor or reciprocating pumps; scroll compressors; hand-operated pumps; global signaling fans; distance adapters; spinel liners; kiln feeder tubes; reflectors; polyester boots; spinnel discs; fresh air intakes; chest freezers; aftercoolers; air dryers; marine engine radiators; roll compactor steel cylinders; water filters; net filters; chlorinators; water tank screen assemblies; filter assemblies; sleeve assemblies; inlet drain valve piping kits; cover assemblies; cartridge weight scales; air guns; mechanical jacks; trolley hoists; universal joints; socket adapters; pneumatic barring over tools; hydraulic main bearing wrenches; hydraulic pump kits; pinion pullers; pin removal tools; tubing; connectors; puller clamp plates; credit card acceptors; automated fare collection systems; laptop computers; toughbooks; tablets; embedded controllers; desktop computers; network servers; processor servers; CPU embedded programmable servers; embedded box PCs; LCD monitors—keyboard enclosures; computer boards; floppy disks; encryption keys; network interface connectors; rocketport interface units; USB to RS–422 adapters; memory chip programmers; handheld barcode scanners; bank note validators; PCB cards; timer boards; electronic integrated circuits; sand traps; copper spring guides; air horns; locomotive air horns; heat sink cleaning systems; fire protection kits; fire protection hoses; locomotive heater assemblies; head tensioners; hydraulic presses; needle roller bearings; bearing inserts; gasket kits; O-ring kits; ball valve repair kits; steel oil seals; AC motors; motor assemblies; DC motor units; cab heater motors; spring charging motors; 3-phase AC motors; AC traction motors; evaporation motors; alternators; generator sets; diesel engine units; AC generator sets; transformers; magnets; magnet mounts; magnetic hardware trays; lithium batteries; battery maintenance kits; DGS downhole battery packs; closure caps; battery grates; current collectors; Ni-CD batteries; Ni-CD battery kits; C9 battery packs; nickel cadmium batteries; OCU finish batteries; lithium ion batteries; sodium hydride batteries; UPS batteries; metal halide batteries; storage batteries; sodium halide batteries; steel battery vents; battery vent caps; industrial vacuums; shop vacuums; solenoid switches; emergency lights; induction heaters; pinion heaters; resistance welders; resistance brazing tongs; water heater assemblies; drain valve heaters; immersion heaters; electric hot plates; heating elements; resistance panel heaters; heat blankets; brake resistors; heat resistance panels; telecom heaters; mica panel heaters; smart telephones; Ethernet base units; amplifiers; blank CDs; flash memory drives; flash cards; diagnostic boards; tags; solid state storage; solid state drove cartridges; cameras; radar sensors; LCR remote radios; operational control remotes; remote control units; radios; CRT monitors; LCD monitors; antennae; GPS simulation boards; GPS–RIM PCBs; rail safety electrologic; railroad traffic safety cases; HXP–3 crossing processors; VHLC systems; enclosures; cab signal generators; sure climb system-fall arrestors; PCB input-output; aluminum UCH LCR enclosures; cab signaling system PCBs; lamp driver modules; aluminum covers; SCX card guides; PCB processors; logic PCBs; alarms; fire suppression detectors; fire alarm modules; heatsink; connection assemblies; silicone keypads; capacitors; tantalum capacitors; resistors; panels; resistor kits; snubber assemblies; rheiostats; potentiometers; varistors; resistor holders; base supports; copper resistor plates; potentiometer adjusters; PCBs; impregnated plastic boards; fuses; load bank fuses; circuit protectors; knife switches; 60A interrupters; voltage isolators; ground blocks; surge protectors; spark arrestors; circuit breakers; breaker backdoors; motor starter panels; sockets; fittings; lamp holders; lamp assemblies; coaxial connector sets; connectors; magnetic antenna mounts; crimp rings; motor control modules; motor control panels; compressor motor panels; steel electronic cases; case assemblies; fiberglass consoles; control group weldments; case weldments; weldments; receptacle enclosures; locotrol panel assemblies; panels; VHLC PCBs; translator input/output PCBs; lamps; headlights; filament bulbs; locomotive shutter assemblies; headlight box assemblies; globe guards; zener diodes; locomotive electrical kits; NPN transistors; transistors; silicone transistors; unmounted transistors; white light assemblies; 120VAC pilot lights; LED lamps; digital isolators; quartz oscillators; LED lens holders; IGBT module housings; IGBT housing covers; LED retaining rings; gate drive circuits; shields; bases; line driver integrated circuits; microprocessors; covers; electronic CPU control units; VIM processors; CPU circuit cards; SRAM memory cards; SDRAM IC, SRAM memory cards integrated circuit amplifiers; gate array integrated circuits; PHE outlet pipe assemblies; analog IC; voltage-regulator, power-management and programmable-logic IC; integrated circuits; contactor tips for controllers; axle pulse generators; HXP–3 PCB assemblies; signal generator subtone converters; speed sensors; turbo speed sensors; sensors; traction motor speed sensors; axle generators; current transducers; magnetic pickup sensors; serial data boards; memory modules; copper winding wires; winding wire magnets; coaxial cables; cables; antenna cables; locomotive wire harnesses; kablo cables; harnesses; AESS kits; auxiliary light arrangement conduit assemblies; telecommunications cables; CMU Ethernet cables; telephone cables; arcnet-ethernet cables; conductors; cable displays; carbon brushes; filter brush kits; carbon brush generators; brushes; traction motor brushes; insulation sleeving; insulator bushing; electrical bushing; insulation; electrical insulators; insulator mica blocks; splice piece insulators; insulator kits; plastic insulators; ceramic insulator leads; thermal pad insulators; ceramic bushings; ferrite chokes; insulator assemblies; mica insulation; insulating shields; fiberglass guards; glastic insulators; insulating collars; mica insulating plates; insulator fittings; mica insulation segments; U-piece insulated fittings; diesel electric locomotives; evolution locomotives; truck assemblies; locomotive truck frames; locomotive axles; axles; flex couplers; steek pins; coupler release levers; knuckles; draft gear assemblies; coupler wear plates; couplers; yokes; spacers; hubs; gears; steel yaw dampeners; machined castings; draft gear links; wear plates; brass couplings; crossing gate kits; gate rail kits; mounting kits; cantilever gates; CTS–2 switch machines; railway cantilevers; signal masts; rack interfaces; tempo system output boards; cantilever arms; gate mechanism assemblies; railway gate arms; CTS–2 steel plates; retarder assemblies; OHV brake retarders; OHV transmissions; AC motorized wheels; torque tubes; brake hubs; locomotive transmissions; carrier castings; OHV carrier assemblies; hub cap kits; longitudinal shafts; ring end torque tubes; truck steel plugs; ring end steel forgings; steel carts; tool cart kits; steel casters; laser quartz lenses; optical lens caps; display enhancement filters; plastic, mounted and locomotive lenses; optical pulse generators; boroscopes; pulse generators; meteorological psychrometers; air flow indicators; drill fixtures; vinyl stencils; carbide scribers; digital micrometers; inside micrometers; hand-held caliper gauges; Vernier calipers; turbo internal micrometers;

digital micrometers; micrometer sets; tape measures; grind gauges; valve checker tools; standard rulers; digital check gauges; metric scales; feeler gauges; handle line up gauges; oxygen masks; water temperature gauges; manifold temperature sensors; digital pyrometer kits; cable sensor kits; fire protection kits; thermal spot detectors; thermal spot sensors; electrical thermo-hygrometers; wireless weather stations; motor bearing detectors; barometers; PCB sensors; HWB thermometers; thermal scanner assemblies; HWD pyroelectric detectors; scanner covers; thermowell fittings; aluminum brackets; tube alignment fixtures; HWB cabinets; sensor brackets; aluminum panels; battery trays; coolant level sensor kits; fuel tank monitors; fuel level electrical sensors; fuel gauges; fuel tank control units; melt level indicators; electric fuel monitoring panels; water-fuel sensors; optical level sensors; dip sticks; pressure sensors; pressure indicators; air pressure gauges; air pressure transducers; MR1 sensors; engine fuel transducers; lube oil pressure sensors; NoX sensors; pneumatic air brake modules; transducer assemblies; flow meters; metal debris sensors; gas flow meters; digital manometers; pressure line adaptors; fuel condition sensor mounts; fuel gauge covers; fuel sensor pipe assemblies; NH3 gas analyzers; oxygen level gas analyzers; digital gas analyzers; spot sensors; carbide dioxide analyzers; soot sensors; leak detectors; battery spectrometers; spectrum monitors; balometer kits; dissolved solids meters; data viewer sensor kits; stations; manifolds; digital hybrid interfaces; heated sample lines; power flow meters; load electrical meters; RPM gauges; fitbits; SWC RCI wheel sensors; high speed counters; train odometers; hub odometers; RPM sensors; wheel counter kits; digital odometers; speedometers; speed sensors; speed indicators; engine speed sensors; wheel sensors; tachometer sensors; diesel sensors; locomotive converter speed indicator boards; handheld tachometers; amplifier isolation panels; speed signal amplifiers; clamping rings; speedometer modules; odometer plates; multimeters; digital, handheld and fluke multimeters; dart digital display units; fluke digital multimeters; locomotive ammeters; analog meters; relay-reset limitors; load meters; power brake ammeters; feedback modules; current module event recorders; current monitors; brake current ammeters; digital ammeters; voltmeters; floe meter monitors; test boxes; locotrol test fixtures; current transducers; amp loadmeters; strain gauges; circuit monitoring modules; AC current probes; copper shunts; locomotive ground detection panels; flash-over protection panels; data acquisition units; electrical impulse panels; digital ohmmeters; transductors; AC data loggers; high voltage testers; megohm testers; lon circuit boards; electronic system periodic testers; spectrum analyzers; hipot test stations; electromagnetic test kits; arbitrary waveform generators; voltage measuring boards; distance sensors; laser motion sensors; electronic levels; torque wrench testers; valve seat seal tests; event recorder modules; function modules; cards; serial cards; ring taper gauges; HAS detector probes; modules; tester interface boards; dial indicator contact points; aluminum enclosures; system temperature sensors; testing panels; thermostat remotes; heater thermostats; voltage regulator 240V scoop; AC control boards; mini-regulators; thermostat seals; hour meters; PCB timer train separation displays; vital timers; time delay modules; timers; hour meter brackets; seat swivels; locomotive seats; swivel seats; seat cushion assemblies; air adjust seats; folding seats; tool stools; back seat protectors; arm rests; pedestal seats; storage racks; computer steel shelves; steel shelves; aluminum cases; mounting arms; steel shelf brackets; pillows and cushions; cab lights; wall lighting fixtures; lamp fixtures; locomotive switch kits; headlight enclosures; ditch light assemblies; warning lights; lamp glass globes; lexan lenses; LED light assembly gaskets; diffusers; light fixture lenses; support steel; ditch light housings; lens door assemblies; headlight shell; lamp shades; dome light panels; doors; aluminum houses; instrument houses; steel wayside houses; pipe wire brushes; wire brushes; paint pens; and, electric ignition units (duty rate ranges from duty-free to 20%). The request indicates that inputs classified under HTSUS Chapter 32 and HTSUS Subheadings 4202.12, 5207.10, 5602.90, 5603.94, 5607.50, 5608.19, 5609.00, 5806.31, 5909.00, 5910.00, 6303.92, 6305.20, 6307.90, 7019.19, 7019.51, and 9404.90 will be admitted to the zone in privileged foreign status (19 CFR 146.41), thereby precluding inverted tariff benefits on such items.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 7, 2014.

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 Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: February 20, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–04224 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and New Shipper Reviews; 2012

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is conducting the eighth administrative review (''AR'') and a new shipper review (''NSR'') of the antidumping duty order on wooden bedroom furniture (''WBF'') from the People's Republic of China (''PRC''). The AR covers 60 exporters of subject merchandise, of which the Department selected three companies for individual examination. The NSR covers one exporter and producer of subject merchandise. The period of review (''POR'') for the AR and NSR is January 1, 2012, through December 31, 2012. The Department preliminarily determines that one of the mandatory respondents in the AR and the respondent in the NSR have made sales of subject merchandise at less than normal value. Additionally, the Department preliminarily determines that it will treat the other two mandatory respondents in the AR as part of the PRC-wide entity. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* February 26, 2014.

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor, Lori Apodaca, or Jeffrey Pedersen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0989,

(202) 482–4551, and (202) 482–2769, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The product covered by the order is wooden bedroom furniture, subject to certain exceptions.[1] Imports of subject merchandise are classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings: 9403.50.9042, 9403.50.9045, 9403.50.9080, 9403.50.9042, 9403.50.9045, 9403.60.8081, 7009.92.1000 or 7009.92.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description in the *Order* remains dispositive.[2]

Methodology

The Department is conducting these reviews in accordance with sections 751(a)(1)(B) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.214. The Department calculated export prices in accordance with section 772 of the Act. Because the PRC is a nonmarket economy (''NME'') within the meaning of section 771(18) of the Act, the Department calculated normal value in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum, which is hereby adopted with this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

PRC-Wide Entity

In the *Initiation Notice* for the AR, we stated that ''for exporters and producers who submit a separate rate application or separate rate certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate-rate status unless they respond to all parts of the questionnaire as mandatory respondents.'' [3] The Department selected Marvin Furniture (Shanghai) Co., Ltd. (''Marvin Furniture''), Foliot/Meubles Furniture Inc., Foliot Pacific, and Foliot Corporation (collectively, ''the Foliot Group''), and Hualing Furniture (China) Co., Ltd., Tony House Manufacture (China) Co., Ltd., Buysell Investments Ltd., and Tony House Industries Co., Ltd. (collectively, ''Tony House Group'') as mandatory respondents.[4] Marvin Furniture failed to answer all sections of the Department's antidumping questionnaire, failed to respond to a supplemental Section A questionnaire, and subsequently withdrew from participating in the AR.[5] The Foliot Group failed to answer two supplemental questionnaires pertaining to its Sections A, C, D, and E responses and also subsequently withdrew from participating in the AR.[6] As such, for the reasons explained in the Preliminary Decision Memorandum, neither Marvin nor the Foliot Group established its eligibility for a separate rate, and, thus, we are treating both companies as part of the PRC-wide entity. The PRC-wide entity rate is 216.01 percent.

In addition, 44 companies that remain under review failed to provide separate rate applications or certifications necessary to establish their eligibility for a separate rate. For a complete list of these companies, see the Preliminary Decision Memorandum. The Department preliminarily determined to treat these 44 companies as part of the PRC-wide entity.

Preliminary Results of Review

Regarding the AR, we preliminarily determine that the following weighted-average dumping margins exist for the period January 1, 2012, through December 31, 2012.

Exporter	Weighted-average dumping margin (percent)
Hualing Furniture (China) Co., Ltd., Tony House Manufacture (China) Co., Ltd., Buysell Investments Ltd., Tony House Industries Co., Ltd	3.81
PRC-wide entity	[7] 216.01

Regarding the NSR, we preliminarily determine that the following weighted-average dumping margin exists for the period January 1, 2012 through December 31, 2012:

Exporter	Producer	Weighted-average dumping margin (percent)
Dongguan Chengcheng Group Co., Ltd	Dongguan Chengcheng Group Co., Ltd	10.71

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture From the People's Republic of China,* 70 FR 329 (January 4, 2005) (''*Order*'').

[2] For a complete description of the Scope of the Order, please see ''*Decision Memorandum for Preliminary Results of Antidumping Duty Administrative and New Shipper Review: Wooden Bedroom Furniture from the People's Republic of China,*'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance (''Preliminary Decision Memorandum''), dated concurrently with this notice.

[3] *See Initiation Notice* at 78 FR 13626, 13628.

[4] *See* Preliminary Decision Memorandum.

[5] *See* Letter from Marvin Furniture to Penny Pritzker, Secretary of Commerce, Re: ''Withdrawal as Mandatory Respondent from the Eighth Administrative Review of Wooden Bedroom Furniture from the People's Republic of China,'' dated July 18, 2013.

[6] *See* Letter from the Foliot Group to Penny Pritzker, Secretary of Commerce, regarding ''Withdrawal as a Mandatory Respondent—Foliot Furniture Inc. Wooden Bedroom Furniture from China,'' dated September 12, 2013.

[7] The PRC-Wide Entity includes Marvin Furniture (Shanghai) Co., Ltd., Foliot Furniture Pacific Inc., Foliot Furniture Corporation, and Foliot Furniture Inc./Meubles Foliot Inc.; and the 44 entities for which the Department initiated a review but which did not establish their separate rate eligibility. *See* the Preliminary Decision Memorandum for the names of the 44 companies.

Disclosure and Public Comment

The Department will disclose calculations performed for these preliminary results to parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[8] Rebuttals to case briefs may be filed no later than five days after the written comments are filed and all rebuttal comments must be limited to comments raised in the case briefs.[9]

Any interested party may request a hearing within 30 days of publication of this notice.[10] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.[11]

The Department will issue the final results of this AR and NSR, which will include the results of its analysis of issues raised in any briefs received, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Deadline for Submission of Publicly Available Surrogate Value Information

In accordance with 19 CFR 351.301(c)(3)(ii), the deadline for submission of publicly available information to value factors of production under 19 CFR 351.408(c) is 20 days after the date of publication of these preliminary results.[12] In accordance with 19 CFR 351.301(c)(1) (2012), if an interested party submits factual information less than ten days before or on the applicable deadline for submission of such factual information, an interested party may submit factual information to rebut, clarify, or correct the factual information no later than ten days after such factual information is served on the interested party. However, the Department generally will not accept in the rebuttal submission additional or alternative surrogate value information not previously on the record, if the deadline for submission of surrogate value information has passed.[13] Furthermore, the Department generally will not accept business proprietary information in either the surrogate value submissions or the rebuttals thereto, as the regulation regarding the submission of surrogate values allows only for the submission of publicly available information.[14]

Assessment Rates

Upon issuing the final results of these reviews, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by these reviews.[15] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of these reviews.

For each individually examined respondent in these reviews whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.5 percent) in the final results of these reviews, the Department will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1).[16] Where an importer- (or customer-) specific *ad valorem* rate is greater than *de minimis,* the Department will instruct CBP to collect the appropriate duties at the time of liquidation.[17] Where either a respondent's weighted average dumping margin is zero or *de minimis,* or an importer- (or customer-) specific ad valorem dumping margin is zero or *de minimis,* the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[18] We intend to instruct CBP to liquidate entries of subject merchandise exported by the PRC-wide entity at the PRC-wide rate.

The Department announced a refinement to its assessment practice in NME cases. Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales database submitted by companies individually examined during the administrative review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. Additionally, if the Department determines that an exporter had no shipments of subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the PRC-wide rate.[19]

Furthermore, Petitioners requested that we issue specific liquidation instructions related to certain entries of Marvin Furniture's and the Foliot Group's subject merchandise. Due to the proprietary nature of these comments, we addressed these comments in a separate memorandum.[20]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of these reviews for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For the companies listed above that have a separate rate, the cash deposit rate will be that rate established in the final results of these reviews (except, if the rate is zero or *de minimis,* then a zero cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the PRC-wide entity; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter.

[8] *See* 19 CFR 351.309(c).

[9] *See* 19 CFR 351.309(d).

[10] *See* 19 CFR 351.310(c).

[11] *See* 19 CFR 351.310(d).

[12] The Department recently announced a change in the deadline to submit publicly available information to value factors of production under 19 CFR 351.301(c)(3)(ii). To all segments initiated on or after May 10, 2013, the deadline to submit publicly available information to value factors of production in an administrative review is 30 days prior to the scheduled preliminary results of review. This change will not apply to the eighth administrative review of wooden bedroom furniture from the PRC due to the effective date. *See Definition of Factual Information and Time Limits for Submission of Factual Information,* 78 FR 21246 (April 10, 2013).

[13] *See, e.g., Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007), and accompanying Issues and Decision Memorandum at Comment 2.

[14] *See* 19 CFR 351.301(c)(3).

[15] *See* 19 CFR 351.212(b).

[16] In these preliminary results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[17] *See* 19 CFR 351.212(b)(1).

[18] *See* 19 CFR 351.212(b)(1).

[19] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[20] *See* Memorandum from Patrick O'Connor to Abdelali Elouaradia, Re: ''2012 Administrative Review of Wooden Bedroom Furniture From the People's Republic of China: Entries Made by Marvin Furniture and the Foliot Group,'' dated concurrently with this notice.

With respect to Dongguan Chengcheng, the new shipper respondent, the Department established a combination cash deposit rate for this company, consistent with its practice, as follows: (1) For subject merchandise produced and exported by Dongguan Chengcheng, the cash deposit rate will be the rate established for Dongguan Chengcheng in the final results of the NSR; (2) for subject merchandise exported by Dongguan Chengcheng, but not produced by Dongguan Chengcheng, the cash deposit rate will be the rate for the PRC-wide entity; and (3) for the subject merchandise produced by Dongguan Chengcheng, but not exported by Dongguan Chengcheng, the cash deposit rate will be the rate applicable to the exporter.

These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: February 18, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

1. Scope of the Order
2. No Shipments
3. Bona Fide Sale Analysis
4. Non-Market Economy Country Status
5. Separate Rates
6. Surrogate Country
7. Economic Comparability
8. Significant Producer of Comparable Merchandise
9. Data Availability
10. Date of Sale
11. Normal Value Comparisons
12. Determination of Comparison Method
13. U.S. Price
14. Normal Value
15. Factor Valuations
16. Currency Conversion

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–819]

Steel Concrete Reinforcing Bar From the Republic of Turkey: Preliminary Negative Countervailing Duty Determination, Preliminary Negative Critical Circumstances Determination, and Alignment of Final Determination With Final Antidumping Determination

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are not being provided to producers and exporters of steel concrete reinforcing bar (rebar) from the Republic of Turkey (Turkey). The period of investigation is January 1, 2012, through December 31, 2012. Interested parties are invited to comment on this preliminary determination.

DATES: *Effective Date:* February 26, 2014.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson or Robert Copyak, Office III, 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) 482–4793 and (202) 482–2209, respectively.

Alignment of Final Countervailing Duty (CVD) Determination With Final Antidumping Duty (AD) Determination

On the same day that the Department initiated this countervailing duty (CVD) investigation, the Department also initiated antidumping duty (AD) investigations of rebar from Mexico and Turkey.[1] The CVD investigation and the AD investigations cover the same merchandise. On February 14, 2014, in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (Act), alignment of the final CVD determination with the final AD determination of rebar from Turkey was requested by the petitioner.[2] Therefore, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), we are aligning the final CVD determination with the final AD determination. Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than July 2, 2014, unless postponed.

Scope of the Investigation

The merchandise subject to this investigation is steel concrete reinforcing bar imported in either straight length or coil form (rebar) regardless of metallurgy, length, diameter, or grade. The subject merchandise is classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) primarily under item numbers 7213.10.0000, 7214.20.0000, and 7228.30.8010. The subject merchandise may also enter under other HTSUS numbers including 7215.90.1000, 7215.90.5000, 7221.00.0015, 7221.00.0030, 7221.00.0045, 7222.11.0001, 7222.11.0057, 7222.11.0059, 7222.30.0001, 7227.20.0080, 7227.90.6085, 7228.20.1000, and 7228.60.6000. Specifically excluded are plain rounds (*i.e.,* non-deformed or smooth rebar). HTSUS numbers are provided for convenience and customs purposes; however, the written description of the scope remains dispositive.

Methodology

The Department is conducting this CVD investigation in accordance with section 701 of the Act. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.[3] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov,* and is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/*

[1] *See Steel Concrete Reinforcing Bar From Turkey: Initiation of Countervailing Duty Investigations,* 78 FR 60831 (October 2, 2013) and *Steel Concrete Reinforcing Bar From Mexico and Turkey: Initiation of Antidumping Duty Investigations,* 78 FR 60827 (October 2, 2013).

[2] *See* Letter from Petitioner regarding ''Request to Align the Countervailing Duty Final Determination With the Antidumping Duty Final Determination'' (February 14, 2014).

[3] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance regarding ''Decision Memorandum for the Preliminary Determination in the Countervailing Duty Investigation of Steel Concrete Reinforcing Bar From the Republic of Turkey,'' dated concurrently with this notice (Preliminary Decision Memorandum).

frn/. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Critical Circumstances

The Department preliminarily determines that critical circumstances do not exist for imports of rebar from Turkey. Although the Department preliminarily determines that Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. and Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S. benefited from programs that are inconsistent with the Subsidies Agreement, the companies' shipment data do not indicate a massive increase in shipments of subject merchandise to the United States. Additionally, the shipment data from the U.S. International Trade Commission's dataweb do not indicate a massive increase in shipments of subject merchandise by the ''all other'' companies. Therefore, we preliminarily determine that critical circumstances do not exist with regard to imports of rebar from Turkey. For further information on the Department's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

Negative Preliminary Determination and Suspension of Liquidation

For this preliminary determination, we have calculated a *de minimis* countervailable subsidy rate for each individually investigated producer/exporter of the subject merchandise. Consistent with section 703(b)(4)(A) of the Act, we are disregarding these rates and preliminarily determine that no countervailable subsides are being provided to producers/exporters of the subject merchandise in Turkey. Because the rates calculated for the individually investigated companies are *de minimis,* the all others rate is also *de minimis.*

We preliminarily determine the countervailable subsidy rates to be:

Company	Subsidy rate (percent (*de minimis*))
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S	0.78
Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S	0.10

Because we preliminarily determine that the CVD rates in this investigation are *de minimis,* we will not direct U.S. Customs and Border Protection to suspend liquidation of entries of the subject merchandise from Turkey.

Disclosure and Public Comment

The Department intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement.[4] Interested parties may submit case and rebuttal briefs. For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act.

Dated: February 19, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Scope Comments
2. Scope of the Investigation
3. Injury Test
4. Critical Circumstances
5. Subsidies Valuation
6. Analysis of Programs
7. ITC Notification
8. Disclosure and Public Comment
9. Verification

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[4] *See* 19 CFR 351.224(b).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–830]

Welded Stainless Pressure Pipe From Thailand: Amended Preliminary Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* February 26, 2014.

SUMMARY: On January 7, 2014, the Department of Commerce (''the Department'') published in the **Federal Register** its preliminary determination that welded stainless pressure pipe (''WSPP'') from Thailand is being, or is likely to be, sold in the United States at less than fair value (''LTFV''), as provided in section 733(b) of the Tariff Act of 1930, as amended (''the Act'').[1] On January 3, 2014, Ametai Co., Ltd. and Thareus Co., Ltd. (''Ametai/Thareus'') notified the Department that it was withdrawing its participation from the LTFV investigation. Based on the circumstances described below, the Department is amending the *Preliminary Determination.* This amended preliminary determination results in revised antidumping duty margins and cash deposit rates.

FOR FURTHER INFORMATION CONTACT: Brandon Farlander, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0182.

SUPPLEMENTARY INFORMATION:

Case History

On December 13, 2013, Petitioners alleged that Ametai/Thareus misled the Department concerning certain affiliation allegations regarding Ametai/Thareus.[2] On December 18, 2013, the Department issued Petitioners a letter requesting clarification regarding certain affiliation allegations in their December 13, 2013, submission.[3] On December 20, 2013, Petitioners filed their response to the Department's December 18, 2013, letter.[4] Additionally, on December 18, 2013, the Department issued Ametai/Thareus a supplemental questionnaire regarding certain affiliation issues.[5] On December 24, 2013, and December 30, 2013, Ametai/Thareus responded to the Department's December 18, 2013, supplemental questionnaire.[6] In the Department's Preliminary Decision

[1] *See Welded Stainless Pressure Pipe From Thailand: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 79 FR 812 (January 7, 2014) (''*Preliminary Determination*'').

[2] *See* Submission from Petitioners, ''Welded Stainless Pressure Pipe from Thailand: Comments on Section D,'' dated December 13, 2013. Petitioners filed their affiliation allegations on December 13, 2013 through Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS'') under the one day lag rule; therefore, for the Department's consideration, the official version of this submission is dated December 13, 2013, although Petitioners filed the final version with a date of December 16, 2013.

[3] *See* Letter from the Department to Petitioners, ''Antidumping Duty Investigation of Welded Stainless Steel Pressure Pipe from Thailand: Clarification Supplemental Questionnaire on December 16, 2013, Section D comments,'' dated December 18, 2013. The Department's December 18, 2013, letter was in response to Petitioners' December 13, 2013, filing but dated December 16, 2013.

[4] *See* Submission from Petitioner, ''Welded Stainless Pressure Pipe from Thailand: Thareus: Petitioners' Response to Department's December 18, 2013 Questionnaire,'' dated December 20, 2013.

[5] *See* Letter from the Department to Thareus, ''Antidumping Duty Investigation of Welded Stainless Steel Pressure Pipe from Thailand: Third Section A Supplemental Questionnaire,'' dated December 18, 2013.

[6] *See* Submissions from Ametai/Thareus, ''Welded Stainless Steel Pressure Pipe From Thailand; Antidumping Duty Investigation; Section A Supplemental Questionnaire Response,'' dated December 24, 2013, and ''Welded Stainless Steel Pressure Pipe From Thailand; Antidumping Duty Investigation; Section A Supplemental Questionnaire Response,'' dated December 30, 2013.

Memorandum, we stated that we intended to continue exploring the affiliation issue for the final determination.[7]

In reviewing Ametai/Thareus' December 24, 2013, and December 30, 2013, supplemental questionnaire responses, and Petitioners' December 13, 2013, and December 20, 2013, affiliation allegations, it was clear that there were unresolved affiliation issues. However, before we could issue an additional supplemental questionnaire, on January 3, 2014, Ametai/Thareus withdrew from participating in this investigation.[8]

On January 7, 2014, we published our *Preliminary Determination.* In the *Preliminary Determination,* the Department calculated a 7.16 percent margin for Ametai/Thareus, and included Ametai/Thareus' 7.16 percent preliminary margin in calculating the ''all others'' rate. On January 9, 2014, Petitioners stated that there were ''strong indications of fraud and certification violations'' and requested that the Department amend its *Preliminary Determination* and apply adverse facts available (''AFA'') to Ametai/Thareus because they had significantly impeded the Department's investigation.[9]

In sum, the Department notes the following facts in this case: (1) Petitioners made certain affiliation allegations regarding Ametai/Thareus; (2) the Department issued Ametai/Thareus a supplemental questionnaire in response to Petitioners' affiliation allegations, to which Ametai/Thareus responded on December 24, 2013, and December 30, 2013; (3) after analyzing Ametai/Thareus' December 24, 2013, and December 30, 2013, responses, the Department determined that an additional supplemental questionnaire to Ametai/Thareus on certain affiliation issues was required in order to clarify the record; (4) on January 3, 2014, before we could issue the questionnaire, Ametai/Thareus withdrew from participating in this investigation; (5) in the *Preliminary Determination,* the Department included Ametai/Thareus' 7.16 percent margin in calculating the ''all others'' rate; and (6) any change to Ametai/Thareus' preliminary margin will have a significant impact on the ''all others'' rate. In light of these facts, the Department finds it necessary to issue an amended preliminary determination.

Period of the Investigation

The period of investigation (''POI'') is April 1, 2012, through March 31, 2013. This period corresponds to the four most recent fiscal quarters prior to the month of the filing of the petition, which was May 2013.[10]

Scope of the Investigation

The merchandise covered by this investigation is circular welded austenitic stainless pressure pipe not greater than 14 inches in outside diameter. For purposes of this investigation, references to size are in nominal inches and include all products within tolerances allowed by pipe specifications. This merchandise includes, but is not limited to, the American Society for Testing and Materials (ASTM) A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications. ASTM A–358 products are only included when they are produced to meet ASTM A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications.

Excluded from the scope are: (1) Welded stainless mechanical tubing, meeting ASTM A–554 or comparable domestic or foreign specifications; (2) boiler, heat exchanger, superheater, refining furnace, feedwater heater, and condenser tubing, meeting ASTM A–249, ASTM A–688 or comparable domestic or foreign specifications; and (3) specialized tubing, meeting ASTM A269, ASTM A–270 or comparable domestic or foreign specifications.

The subject imports are normally classified in subheadings 7306.40.5005, 7306.40.5040, 7306.40.5062, 7306.40.5064, and 7306.40.5085 of the Harmonized Tariff Schedule of the United States (HTSUS). They may also enter under HTSUS subheadings 7306.40.1010, 7306.40.1015, 7306.40.5042, 7306.40.5044, 7306.40.5080, and 7306.40.5090. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the investigation is dispositive.

Adverse Facts Available

Sections 776(a)(1) and (2) of the Act provide that the Department shall apply ''facts otherwise available'' if, *inter alia,* necessary information is not on the record or an interested party: (A) Withholds information requested by the Department, (B) fails to provide such information by the deadline, or in the form or manner requested, (C) significantly impedes a proceeding, or (D) provides information that cannot be verified, as provided by section 782(i) of the Act.

Where the Department determines that a response to a request for information does not comply with the request, section 782(d) of the Act provides that the Department will so inform the party submitting the response and will, to the extent practicable, provide that party the opportunity to remedy or explain the deficiency. If the party fails to remedy the deficiency within the applicable time limits, the Department may disregard all or part of the original and subsequent responses, subject to section 782(e) of the Act, as appropriate. Pursuant to section 782(e) of the Act, the Department shall not decline to consider submitted information if all of the following requirements are met: (1) The information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability; and (5) the information can be used without undue difficulties.

On January 3, 2014, Ametai/Thareus informed the Department that it would not continue to participate in the instant investigation. Pursuant to sections 776(a)(2)(C) and (D) of the Act, facts available is warranted in calculating the antidumping duty margin for Ametai/Thareus. We determined that Ametai/Thareus significantly impeded the proceeding by ceasing to participate in the instant investigation prior to the Department issuing an additional supplemental questionnaire on certain affiliation issues, thus preventing the Department from gathering additional facts on these affiliation issues and clarifying the record. Additionally, by ceasing its participation, Ametai/Thareus prevented the Department from conducting verification of the information the company submitted. For these reasons, we find that the use of facts available, pursuant to sections 776(a)(2)(C) and (D) of the Act is appropriate in determining the

[7] *See* ''Decision Memorandum for the Preliminary Determination of Antidumping Duty Investigation: Welded Stainless Pressure Pipe From Thailand,'' (''Preliminary Decision Memorandum'') from Abdelali Elouaradia, Director, Office IV, Antidumping and Countervailing Duty Operations, to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, dated December 30, 2013.

[8] *See* Submission from Ametai/Thareus, ''Welded Stainless Pressure Pipe from Thailand: Notice of Intent Not to Participate in Antidumping Duty Investigation and Request of Removal from Public and APO Service Lists,'' dated January 3, 2014.

[9] *See* Submission from Petitioners, ''Welded Stainless Pressure Pipe from Thailand: Thareus: Request for Amended Preliminary Determination,'' dated January 9, 2014 at 2.

[10] *See* 19 CFR 351.204(b)(1).

applicable dumping margin for Ametai/Thareus.

Section 776(b) of the Act provides that, in selecting from among the facts otherwise available, the Department may employ an adverse inference if an interested party fails to cooperate by not acting to the best of its ability to comply with requests for information.[11] In the instant case, we determined that applying section 776(b) of the Act is warranted for Ametai/Thareus. This determination is based on the fact that Ametai/Thareus' withdrawal from participation prevented the Department from fully investigating certain affiliation allegations and verifying the information submitted to the Department, thus constituting a failure of Ametai/Thareus to cooperate to the best of its ability.

Section 776(b) of the Act authorizes the Department to use, as AFA, information derived from the petition, the final determination from the LTFV investigation, a previous administrative review, or any other information placed on the record. In selecting a rate for AFA, the Department selects one that is sufficiently adverse ''as to effectuate the purpose of the facts available rule to induce respondents to provide the Department with complete and accurate information in a timely manner.'' [12] It is the Department's practice to select, as AFA, the higher of the (a) highest margin alleged in the petition, or (b) the highest calculated rate for any respondent in the investigation.[13] Accordingly, to ensure that the non-cooperative party, Ametai/Thareus, does not benefit from its lack of participation, and to select a sufficiently adverse rate to induce cooperation in the future, for the amended preliminary determination, we selected the higher of either the highest margin alleged in the petition or the highest weighted-average calculated rate for any respondent in the investigation. The weighted-average margins for Ametai/Thareus and the other mandatory respondent, Thai-German Products Public Company Limited (''TGP''), in the *Preliminary Determination* were less than the 24.01 percent margin from the petition. Therefore, consistent with its practice, the Department selected the highest margin alleged in the petition, which is 24.01 percent, as the AFA rate assigned to Ametai/Thareus.

Section 776(c) of the Act provides that, when the Department relies on secondary information in using the facts otherwise available, it must, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal. We have interpreted ''corroborate'' to mean that we will, to the extent practicable, examine the reliability and relevance of the information submitted to satisfy ourselves that the secondary information has probative value.[14] In this instant case, to corroborate the 24.01 percent margin used as AFA for Ametai/Thareus, we relied on the pre-initiation analysis of the adequacy and accuracy of the information in the petition as well as transaction-specific margins [15] for mandatory respondent TGP from the *Preliminary Determination*.[16]

During the initiation stage, we examined evidence supporting the calculations in the petition and the supplemental information provided by Petitioners to determine the probative value of the margins alleged in the petition.[17] During our pre-initiation analysis, we examined the information used as the basis of export price and normal value (''NV'') in the petition, and the calculations used to derive the alleged margins.[18] Also, during our pre-initiation analysis, we examined information from various independent sources provided either in the petition or, based on our requests, in supplements to the petition, which corroborated key elements of the export price and NV calculations.[19] Therefore, for the final determination, the Department finds that the rates derived from the petition for purposes of initiation have probative value for the purpose of being selected as the AFA rate assigned to Ametai/Thareus. In addition, transaction-specific margins from TGP from the *Preliminary Determination* which are higher than the petition rate of 24.01 percent also corroborate the petition rate.

All Others Rate

The ''All Others'' rate is derived exclusive of all *de minimis* or zero margins and margins based entirely on AFA. In the *Preliminary Determination,* the Department calculated the ''all others'' rate, in part, based on Ametai/Thareus' *Preliminary Determination* rate. In light of Ametai/Thareus' withdrawal from the investigation and the Department's subsequent application of total AFA, this methodology for calculating the ''all others'' rate is no longer appropriate. In this case, there is another mandatory respondent, TGP, which received a calculated rate. Therefore, consistent with Department practice, we will apply TGP's rate as the ''all others'' rate in this amended preliminary determination.[20]

Amended Preliminary Determination Margins

The Department determined that the following amended preliminary dumping margins exist for the POI:

Manufacturer/exporter	Weighted-average dumping margin (%)
Ametai Co., Ltd./Thareus Co., Ltd	24.01
Thai-German Products Public Company Limited	* 10.92
All Others	10.92

* Unchanged from the *Preliminary Determination.*

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing U.S. Customs and Border Protection (''CBP'') to suspend liquidation of all entries of WSPP from Thailand, as described in

[11] *See Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon Quality Steel Products from the Russian Federation,* 65 FR 5510, 5518 (February 4, 2000); *Certain Welded Carbon Steel Pipes and Tubes From Thailand: Final Results of Antidumping Duty Administrative Review,* 62 FR 53808, 53819–20 (October 16, 1997); *Crawfish Processors Alliance* v. *United States,* 343 F. Supp.2d 1242 (CIT 2004) (approving use of AFA when respondent refused to participate in verification); *see also Statement of Administrative Action,* accompanying the Uruguay Round Agreements Act (''URAA''), H.R. Rep. No. 103–316, 870 (1994) (''SAA'').

[12] *See Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors From Taiwan,* 63 FR 8909, 8932 (February 23, 1998).

[13] *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Orange Juice from Brazil,* 71 FR 2183, 2185 (January 13, 2006).

[14] *See Certain Cold-Rolled Flat-Rolled Carbon-Quality Steel Products From Brazil: Notice of Final Determination of Sales at Less Than Fair Value,* 65 FR 5554, 5568 (February 4, 2000).

[15] These transaction-specific dumping margins are based on TGP's sales of subject merchandise during the period under consideration. Therefore, the transaction-specific dumping margins higher than the petition rate of 24.01 percent reflects dumping that has already occurred and are based on rates using TGP's pricing and cost information that was provided in this segment of the proceeding.

[16] *See* Petitions for the Imposition of Antidumping Duties on Imports of Welded Stainless Pressure Pipe from Malaysia, Thailand, and Vietnam, dated May 16, 2013 (Petitions); *see also* Supplement to the Thailand Petition, dated May 24, 2013; *Welded Stainless Pressure Pipe From Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Antidumping Duty Investigations,* 78 FR 35253 (June 12, 2013) (''*Initiation Notice''*); Antidumping Duty Investigation Initiation Checklist: Welded Stainless Pressure Pipe from Thailand (''Thailand Checklist'') dated June 5, 2013; TGP Preliminary Analysis Memorandum, dated December 30, 2013.

[17] *See* Thailand Checklist.

[18] *Id.*

[19] *Id.*

[20] *See Notice of Final Determination of Sales at Less Than Fair Value: Citric Acid and Certain Citrate Salts from Canada,* 74 FR 16843 (April 13, 2009).

the scope of the investigation section, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**.

Pursuant to 19 CFR 351.205(d), we will instruct CBP to require a cash deposit [21] equal to the weighted-average amount by which the NV exceeds Export Price, as indicated in the chart above. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 733(f) of the Act, we notified the International Trade Commission (''ITC'') of our amended preliminary determination. If our final determination is affirmative, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of WSPP from Thailand, or sales (or the likelihood of sales) for importation, of the subject merchandise within 45 days of our final determination.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: February 20, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–04222 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–DS–P

[21] *See Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations,* 76 FR 61042 (October 3, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

Travel and Tourism Trade Mission to Taiwan, Japan and Korea

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice; cancellation.

SUMMARY: The United States Department of Commerce, International Trade Administration, Industry and Analysis previously published a document in the **Federal Register** on June 7, 2013, 78 FR 34344, regarding the Travel and Tourism Trade Mission to Taiwan, Japan and Korea scheduled for March 10–14, 2014. This mission has been cancelled. Please update the existing notice with a note that this mission is cancelled as a February 19, 2014.

FOR FURTHER INFORMATION CONTACT: Frank Spector, Industry and Analysis, Trade Promotion Programs, Phone: 202–482–2054; Fax: 202–482–9000, Email: *Frank.Spector@trade.gov*.

Cancellation Notice

In the **Federal Register** Notice of June 7, 2013, 78 FR 34344 on page 34344, title note at top of page, correct the subject heading of the notice to read: Travel and Tourism to Taiwan, Japan and Korea has been cancelled, March 10–14, 2014.

Dated: February 19, 2014.

Elnora Moye,

Trade Program Assistant.

[FR Doc. 2014–04120 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD152

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel and the Mackerel, Squid, and Butterfish Advisory Panel are meeting to provide input to the Council on potential options to modify the Scup Gear Restricted Areas.

DATES: The meeting will be held on Tuesday, March 18, 2014, from 1 p.m. until 4 p.m.

ADDRESSES: The meeting will be held via webinar with a listening station also available at the Council address below. Webinar link: *http://mafmc.adobeconnect.com/scupgras/*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council is considering modification to the Scup Gear Restricted Areas through Framework 8 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan. This meeting will provide the Council with input on specific alternatives that could be included in this Framework action to modify these gear restricted areas.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: February 21, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–04185 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD150

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council will hold a workshop to discuss the potential governance challenges arising from the impacts of climate change on East Coast marine fisheries.

DATES: The meeting will begin on Wednesday, March 19, 2014 at 1 p.m. and will end on Friday, March 21, 2014 at 12:30 p.m.

ADDRESSES:

Meeting address: The meeting will be held at The Westin Washington, DC City

Center 1400 M Street Northwest, Washington, DC 20005.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this workshop is to convene East Coast fishery managers to explore the existing and potential impacts of climate change on East Coast fisheries governance and identify key management questions, concerns, and information needed to guide future research and coordination between management bodies. Participants will work collaboratively to develop specific next steps for addressing climate change and fisheries governance issues. Invited participants include managers and staff of the New England Fishery Management Council (NEFMC), Mid-Atlantic Fishery Management Council (MAFMC), South Atlantic Fishery Management Council (SAFMC), Atlantic States Marine Fisheries Commission (ASMFC), and NOAA Fisheries (NMFS).

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office (302) 526–5251 at least five days prior to the meeting date.

Dated: February 21, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–04183 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD144

Revisions to NOAA's Policy for the Assessment of Civil Administrative Penalties and Permit Sanctions

AGENCY: Office of General Counsel (OGC), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) announces the availability of draft revisions to NOAA's Policy for the Assessment of Civil Administrative Penalties and Permit Sanctions (Penalty Policy) for public review and comment. The revisions to the policy will improve enforcement consistency nationally, increase predictability in enforcement, improve transparency in enforcement, and more effectively protect natural resources.

DATES: The draft revisions to the Penalty Policy will remain available for public review until April 28, 2014. To ensure that comments will be considered, NOAA must receive written comments by April 28, 2014.

ADDRESSES: Interested persons may submit comments by any of the following methods:

- *Electronic Submissions:* Submit electronic public comments to *penaltypolicy@noaa.gov*;
- *Fax:* 301–427–2211; Attn: Robert Hogan;
- *Mail:* Enforcement Section, Office of the General Counsel, National Oceanic and Atmospheric Administration, 1315 East West Highway, SSMC–3–15424, Silver Spring, MD 20910, Attn: Robert Hogan.

The draft revisions to the Penalty Policy are available electronically at the following Web site: *http://www.gc.noaa.gov/documents/enforcement/draft-penalty-policy.pdf*. Commenters may also request a hard copy of the draft revisions to the Penalty Policy by sending a self-addressed envelope (size 8.5 x 11 inches) to the street address provided above. Comments submitted in response to this notice are a matter of public record. Before including an address, phone number, email address, or other personal identifying information in a comment, please be aware that comments—including any personal identifying information—can and will be made publicly available. While a request can be made to withhold personal identifying information from public review, NOAA cannot ensure that it will be able to do so.

FOR FURTHER INFORMATION CONTACT: Robert Hogan at the above address or by telephone at 301–427–8283.

SUPPLEMENTARY INFORMATION: The draft revisions to the Penalty Policy are intended to provide updated guidance for the assessment of civil administrative penalties and permit sanctions under the statutes and regulations enforced by NOAA. As explained more fully in the text of the Penalty Policy, the purpose of the Policy is to ensure that: (1) Civil administrative penalties and permit sanctions are assessed in accordance with the laws that NOAA enforces in a fair and consistent manner; (2) penalties and permit sanctions are appropriate for the gravity of the violation; (3) penalties and permit sanctions are sufficient to deter both particular violators and the regulated community from committing violations; (4) economic incentives for noncompliance are eliminated; and (5) compliance is expeditiously achieved and maintained to protect natural resources.

Under the draft revisions to the Penalty Policy, NOAA expects to continue to improve consistency at a national level, provide greater predictability for the regulated community and the public, improve transparency in enforcement, and more effectively protect natural resources. The major changes to the existing Penalty Policy made by this draft revision include:

(1) Addition of more detail in some penalty schedules to better describe the most commonly-occurring violations;

(2) Clearer distinctions among multiple-level violations to ensure consistent application of the Penalty Policy;

(3) Revision of the treatment of prior violations so that prior adjudicated violations older than 5 years are no longer considered an aggravating factor;

(4) Ensuring consistent application of the Penalty Policy to recreational offenses by replacing the commercial/recreational distinction as a penalty adjustment factor with additional Level I and II penalties that capture recreational violations;

(5) Creating a new penalty adjustment for ''such other matters as justice may require'' by combining the ''Activity After Violation'' factor with new considerations.

When finalized, the revised Penalty Policy will supersede the previous

Penalty Policy regarding the assessment of penalties or permit sanctions, and previous penalty and permit sanction schedules issued by the NOAA Office of the General Counsel. This Penalty Policy provides guidance for the NOAA General Counsel's Office in assessing penalties but is not intended to create a right or benefit, substantive or procedural, enforceable at law or in equity, in any person or company. NOAA retains discretion to assess the full range of penalties authorized by statute in any particular case.

The full draft revisions to the Penalty Policy, along with examples, matrixes, and schedules, can be found at *http://www.gc.noaa.gov/documents/enforcement/draft-penalty-policy.pdf*. NOAA is seeking public comment on all portions of the Penalty Policy, but specifically asks for comment on the above identified major changes to the existing Penalty Policy.

Dated: February 21, 2014.

Benjamin Friedman,

Deputy General Counsel, National Oceanic and Atmospheric Administration.

[FR Doc. 2014–04195 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD149

Gulf of Mexico Fishery Management Council; Public Hearings

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

ACTION: Notice; public hearings.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold public hearings for Red Snapper Allocation—Amendment 28.

DATES: The public hearings will be held from Monday, March 10 through Monday, March 24, 2014 at nine locations throughout the Gulf of Mexico. The public hearings will begin at 6 p.m. and will conclude no later than 9 p.m. There will be a ''call-in session'' on Thursday March 20th; instructions will be available on our Web site. For specific dates and locations, see **SUPPLEMENTARY INFORMATION** below.

ADDRESSES: *Meeting address:* The public hearings will be held in the following locations: Orange Beach and Mobile, AL; Gulfport, MS; Panama City and St. Petersburg, FL; Kenner, LA; and Corpus Christi, San Antonio and League City/Webster, TX.

Council address: Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Dr. Assane Diagne, Economist, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *assane.diagne@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The items of discussion in the public hearings are as follows:

Red Snapper Allocation—Amendment 28

Consider the reallocation of red snapper resources between the commercial and recreational sectors.

The public hearings will begin at 6 p.m. and conclude at the end of public testimony or no later than 9 p.m. at the following locations:

Monday, March 10, 2014, Fairfield Inn & Suites by Marriott, 3111 Loop Road, Orange Beach, AL 36561, (251) 543–4444;

Tuesday, March 11, 2014, Renaissance Riverview Plaza Hotel, 64 South Water Street, Mobile, AL 36602, (251) 438–4000;

Wednesday, March 12, 2014, Holiday Inn Select, 2001 N. Cove Boulevard, Panama City, FL 32405, (850) 769–0000; Courtyard Marriott Gulfport Beachfront, 1600 East Beach Boulevard, Gulfport, MS 39501, (228) 864–4310;

Thursday, March 13, 2014, La Quinta Inn & Suites New Orleans Airport, 2610 Williams Boulevard, Kenner, LA 70062, (504) 466–1401;

Monday, March 17, 2014, Hilton Garden Inn, 6717 South Padre Island Drive, Corpus Christi, TX 78412, (361) 991–8200;

Tuesday, March 18, 2014, Embassy Suites San Antonio International Airport, 10110 US Hwy 281 N., San Antonio, TX 78216 (201) 525–9999;

Wednesday, March 19, 2014, Hilton Garden Inn Houston/Clear Lake NASA, 750 W. Texas Avenue, Webster, TX 77598, (281) 332–6284;

Thursday, March, 20, 2014, call-in session; visit *www.GulfCouncil.org* for instructions.

Monday, March 24, 2014, Hilton Carillon St. Petersburg, 950 Lake Carillon Drive, St. Petersburg, FL 33716, (727) 540–0050.

Copies of the public hearing documents can be obtained by calling 813–348–1630 or visiting *www.GulfCouncil.org.*

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these hearings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These hearings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: February 20, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–04070 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD123

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to San Nicolas Island Roads and Airfield Repairs Project

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received an application from the Department of the Navy (Navy), Naval Base Ventura County (NBVC), California, for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to the San Nicolas Island (SNI) roads and airfield repairs project. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to NBVC to incidentally take, by Level B harassment only,

marine mammals during the specified activity.

DATES: Comments and information must be received no later than March 28, 2014.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Supervisor, Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *ITP.Nachman@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 25-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm* without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

An electronic copy of the application containing a list of the references used in this document and the Navy's 2012 Environmental Assessment (EA) may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Candace Nachman, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking, other means of effecting the least practicable impact on the species or stock and its habitat, and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: ''any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

Summary of Request

On October 23, 2013, we received an application from the Navy for the taking of marine mammals incidental to the SNI roads and airfield repairs project. NMFS determined that the application was adequate and complete on November 6, 2013.

The Navy proposes to repair roads and the airfield on SNI, California. The proposed activity would occur from August 1 through November 30, 2014, with two separate deliveries of materials to the island during this time period. Each delivery requires approximately 5 days to complete. The following specific aspects of the proposed activities are likely to result in the take of marine mammals: barge beach landings, offloading, and removal and construction activities to prepare for barge landings. Take, by Level B harassment only, of northern elephant seal (*Mirounga angustirostris*), California sea lion (*Zalophus californianus*), and Pacific harbor seal (*Phoca vitulina richardsi*) is anticipated to result from the specified activity.

Description of the Specified Activity

Overview

NBVC plans to perform a maintenance and mission-critical infrastructure project at SNI to repair the roads and airfield. The proposed action would repair up to 12.45 mi of roads and culverts during two phases and one million ft^2 of airfield surface, shoulders, and airfield culvert repair. The SNI roads and shoulder repairs will require approximately 43,500 tons of aggregate materials. Airfield repairs require approximately 151,500 tons of aggregate material. The required aggregate is not available on the island and must be delivered from the mainland. The pier at Daytona Beach is used for transfer of supplies to the island but is not designed to handle large volumes of heavy aggregate. The Navy, therefore, proposes to use barge beach landings on Daytona and Coast Guard Beaches for offloading materials and equipment needed to complete this maintenance and mission-critical infrastructure project. Aggregate would be shipped from the mainland U.S. to the off-shore area of SNI on a primary shipping barge (13,000-ton capacity). The aggregate would be transferred from the primary shipping barge to a smaller ''tender'' barge (2,000-ton capacity) that would land on the beach. Aggregate would be transferred from the shipping barge to the tender barge using a conveyor belt or loaders, then from the tender barge to dump trucks on shore using either loaders or conveyor belts. A typical barge landing operation includes: Re-grading the existing road from the beach; constructing a temporary ramp and berm on the beach; landing the barge; offloading the barge; removing the ramp and berm; and restoring the beach to its pre-barge landing condition.

The Navy identified the proposed work as critical to maintaining mission readiness: The current degraded road is a safety concern for ordnance and operations transport; culvert repairs are necessary to reduce erosion and sedimentation; and mission-critical repairs are required at the SNI runway that is currently degraded by sinkholes and surface deformations.

Dates and Duration

Up to four separate deliveries would occur each year for 5 years. One shipment of 13,000 tons of aggregate would require eight beach landings over 5 days (approximately two landings per day, 4 hours for each operation). Site preparation would take approximately 1 day, and the landings would occur over the remaining 4 days. Because both beaches are haul-out sites for California sea lions, harbor seals and northern elephant seals, beach landings would occur from August 1 through November 30, outside the breeding season when these species are present only sporadically, and in lower numbers than in other times of the year.

This IHA request is only for the period of August 1 through November

30, 2014. NBVC intends to submit an application requesting regulations and a Letter of Authorization to cover these and other activities for a 5-year period later in 2014. Table 1 outlines the proposed delivery schedule for this proposed project.

TABLE 1—BARGE DELIVERY SUMMARY OVER THE 5-YEAR SPAN OF THE PROJECT

Project	Material required	Number of primary shipping barge deliveries	Estimated delivery schedule	
Roads Repair (Phase I and Phase II).	43,500 tons	*3	Year 1	2 × 13,000 tons.
			Year 2	1 × 8,100 tons.
			Year 3	1 × 9,400 tons.
Airfield repairs	151,500 tons	**12	Year 2	2 × 13,000 tons. 1 × 4,900 tons.
			Year 3	3 × 13,000 tons. 1 × 3,600 tons.
			Year 4	3 × 13,000 tons.
			Year 5	3 × 13,000 tons.

*Three primary barge shipments for roads repair includes two full 13,000 ton shipments, and two co-mingled shipments, shared with airfield aggregate material (8,100 tons in Year 2 and 9,400 tons in Year 3).

**Twelve primary barge shipments for airfield repairs includes eleven full 13,000 ton shipments, and two co-mingled shipments shared with road repair aggregate material (4,900 tons in Year 2 and 3,600 tons in Year 3).

Specified Geographic Region

SNI is the outermost of eight Channel Islands off the coast of southern California, 63 nautical miles south-southwest of Laguna Point at NBVC Point Mugu and 75 nautical miles southwest of Los Angeles (see Figure 1 in the IHA application). SNI is owned by the Navy and is under the jurisdiction of NBVC. The island is approximately 9 mi long and 3.6 mi wide. Access to the island by the public is strictly controlled for security reasons and to safeguard against potential hazards associated with military operations. The main support and operational facilities on SNI include an airfield runway and terminal, housing and administration facilities, a power plant, a fuel farm, a reverse osmosis potable water system, and a public works and transportation department.

Daytona Beach is a wide sandy beach at the south end of SNI, the most sheltered part of the island (see Figure 1 in the IHA application). Water depth and soft bottom conditions off-shore support barge anchoring and beach landings. Beach Road is an all-weather paved access road that terminates at Daytona pier and a staging area. The equipment staging area is paved and equipped with electric light poles and adequate space for pier offloads. The staging area is enclosed by k-rails that would be temporarily moved to allow access to the beach-landed barge. The Navy has made barge beach landings at Daytona Beach many times in the past.

Coast Guard Beach is a sandy beach in a relatively sheltered part of the island at the east side of SNI, accessible by Beach Road (see Figure 1 in the IHA application). The Navy has used this site successfully in the past for barge deliveries. On Coast Guard Beach, there is approximately 300 ft from the access road to the high tide line. Coast Guard Beach has a gentler slope than Daytona Beach. The nearshore bottom is soft, and water depths of 2 to 5 ft are suitable for beach landings. Existing moorings in the area may potentially be used as anchorage points for the primary shipping barge. A short (0.1 mi) unpaved road that connects Coast Guard Beach to the proposed asphalt batch plant site would require re-grading to facilitate materials transport. To facilitate re-grading the access road, approximately 400 yd^3 of dirt would be used from the Former Borrow Pit, and additional material would be sourced from the Monroe Borrow Pit if necessary. A shallow surface scrape of six inches would occur across the Former Borrow Pit site to collect material for the access road. Re-grading would provide access widths from 30 to 12.5 ft wide and a smoother surface for hauling.

Detailed Description of Activities

The proposed action would repair up to 12.45 mi of roads and culverts during two phases, and one million ft^2 of airfield surface, shoulders, and airfield culvert repair. The SNI roads and shoulder repairs will require approximately 43,500 tons of aggregate materials. Airfield repairs require approximately 151,500 tons of aggregate material. The required aggregate is not available on the island and must be delivered from the mainland. The pier at Daytona Beach is used for transfer of supplies to the island but is not designed to handle large volumes of heavy aggregate. The Navy, therefore, proposes to use barge beach landings on Daytona and Coast Guard Beaches for offloading materials and equipment needed to complete this maintenance and mission-critical infrastructure project. Aggregate would be shipped from the mainland U.S. to the off-shore area of SNI on a primary shipping barge (13,000-ton capacity). The aggregate would be transferred from the primary shipping barge to a smaller ''tender'' barge (2,000-ton capacity) that would land on the beach. Aggregate would be transferred from the shipping barge to the tender barge using a conveyor belt or loaders, then from the tender barge to dump trucks on shore using either loaders or conveyor belts. Best management practices will be instituted to prevent spills into the ocean during the aggregate offloading process.

The Navy proposes to land the tender barges at either Daytona Beach or Coast Guard Beach, depending on wind and swell conditions at the time of the landing. If conditions are favorable to land at either beach the Navy will select the beach with fewer pinnipeds and

western snowy plovers. Up to four separate deliveries would occur each year for 5 years. One shipment of 13,000 tons of aggregate would require eight beach landings over 5 days (approximately two landings per day, 4 hours for each operation).

The delivery process consists of:

Site Preparation: Site preparation would begin the day before the tender barge arrives. An authorized biologist would move any harbor seals, sea lions, or elephant seals in the immediate area. Elephant seals may require active displacement in the work zone, which would be done by an authorized biologist. A biologist would remain onsite if any marine mammals are to be displaced during barge operations. Pinnipeds will only be displaced if they are within the heavy equipment work zone, which extends 200 feet on both sides of the landing site. A temporary sand ramp would be configured using bulldozers to push, grade, and compact sand perpendicular to the shoreline. The ramp would require moving about 20 yd^3 of beach sand at Daytona Beach, or a smaller volume of sand at Coast Guard Beach because of its more gradual slope. Sand would be moved only above the high tide line. The amount of sand to be moved is a function of the beach slope for each landing site. Two tractors would be positioned 100 ft on either side of the landing area before the tender barge arrives to provide stable anchorage for the tender barge. A set of chains and cables would be attached to each tractor to secure the tender barge.

Barge Delivery: The primary shipping barge would drop anchor approximately 650 ft off-shore in about 24 ft of water at Coast Guard Beach and 45 ft of water at Daytona Beach. The tender barge would tie off to the primary shipping barge while the materials are being transferred. Materials would be offloaded to the tender barge using a conveyor belt or loader. Best Management Practices will be in place to minimize spillage into the ocean.

Barge Beach Landing: Once the tender barge is loaded with approximately 2,000 tons from the primary shipping barge, it would cast off and the tug boat would push it onto the beach. The tender barge would be tethered to each of the two bulldozers, positioned approximately 200 ft apart on the beach. Hydraulic winches on the tender barge would tighten the chains and secure the barge. Once the tender barge is stabilized, fiberglass matting may be laid over the temporary sand ramp, if necessary, to provide a stable surface and allow traction for vehicles during loading and unloading. Previous material transfers onto the beaches have not required matting due to stable sand surfaces. The bulldozers at the barge and ramp interface would ensure that the anchoring remains stable during unloading.

Offloading: Aggregate would be offloaded from the tender barge either by loaders that load dump trucks or by a conveyor belt directly from the barge to dump trucks. Super10 truck and truck tractor/trailer support vehicles would be transported to SNI before the material is delivered using the Navy supply barge and Navy pier.

Barge Removal: After all offloading operations are complete, crew members would remove any fiberglass matting from the temporary ramp and the bulldozers would redistribute the sand above the high-tide line and contour the beach to its previous topography. The anchoring cables and chains would be released and stored off site for future use. The tug would pull the barge away from the beach.

Noise generated at the temporary asphalt batch plant that would be located approximately 300 ft uphill from Coast Guard Beach would be approximately 66.5 decibels (dB) at Coast Guard Beach. The beach is lower than the temporary asphalt batch plant, and noise from the plant would likely be inaudible at this distance over ambient sound at the surf zone. Given the low level of noise being generated and the distance from the beach, noise from the asphalt batch plant would not be expected to adversely affect pinnipeds at Coast Guard Beach.

The barge landing and materials offload could temporarily displace marine mammals from their onshore haulouts, resulting in their movement into the water or down-beach. During barge landings, marine mammals may avoid the proposed project area and haul out at other beach areas. During barge landings and material off-loadings, the Navy biologist or qualified project biologist will monitor and displace pinnipeds from the landing site as necessary for the safety of the marine mammals and construction workers. Temporary barriers will be used, if necessary, to keep the displaced pinnipeds from re-entering the area. No marine mammal mortalities or injuries are expected from the activity.

Description of Marine Mammals in the Area of the Specified Activity

Three species of pinnipeds occur regularly on SNI: Northern elephant seal; California sea lion; and Pacific harbor seal. These species are protected under the MMPA and are not listed under the Endangered Species Act (ESA). These three species are expected in small numbers on Daytona and Coast Guard Beaches from August 1 through November 30. One northern fur seal (*Callorhinus ursinus*) has been seen hauling out with a pup on SNI the past few years (G. Smith, Navy biologist, pers. comm.); however, the sightings are infrequent and not expected to occur within the proposed activity area. Single individuals of Guadalupe fur seal (*Arctocephalus townsendi*) have been intermittently observed over the last few years hauled out along the southwest portion of SNI. Records indicate that they are not likely to occur on the eastern portion of SNI, where the proposed activities would occur. Therefore, these two species are not considered further in this notice.

There are not expected to be any ''takes'' of cetaceans due to their rare occurrence of the inshore waters at SNI. Any cetaceans or marine mammals in the water surrounding barge landing areas would not be affected by the activities, since the distance from the project site precludes the potential for visual disturbance. A small translocated population of approximately 50 southern sea otters (*Enhydra lutris nereis*) occurs on SNI. This species is managed by the U.S. Fish and Wildlife Service and is not considered further in this proposed IHA notice.

Table 2 in this document outlines the status, occurrence, seasonality, and abundance of the three marine mammal species most likely to occur in the proposed project area. The Navy's IHA application contains additional detail on the presence and life history of these species. More information can also be found in the NMFS Stock Assessment Report available online at: *http://www.nmfs.noaa.gov/pr/sars/pdf/po2012.pdf*. A short summary of the distribution, seasonal distribution, and life history information is provided next.

TABLE 2—ESA STATUS, OCCURRENCE, SEASONALITY IN THE PROJECT AREA, AND ABUNDANCE OF THE SPECIES MOST LIKELY TO OCCUR IN THE PROPOSED PROJECT AREA

Common name	Scientific name	Status	Occurrence	Seasonality	Abundance
Northern elephant seal	*Mirounga angustirostris*	NL	Common	Mostly December-mid-May.	124,000
California sea lion	*Zalophus californianus*	NL	Common	Year round	296,750
Pacific harbor seal	*Phoca vitulina richardsi*	NL	Occasional to common	Mostly February-June	30,196

NL = Not listed under the ESA.

Northern Elephant Seal

SNI is the second largest elephant seal rookery and hauling ground in the Southern California Bight (Lowry, 2002). Each year, approximately 30% (23,000 individuals) of the elephant seals hauling out on all California shorelines haul out at SNI on Daytona Beach and Coast Guard Beach. Currently, elephant seals haul out at Daytona and Coast Guard barge landing areas from December through mid-May. This time frame encompasses the breeding season and the female and juvenile molting period. Adult males have been known to haul out at both Daytona and Coast Guard Beaches through August (Lowry, 2002). In 2002, the estimated number of individuals at Daytona Beach was more than 2,000 (U.S. Navy, 2002).

In general, northern elephant seals primarily breed and give birth on off-shore islands, including the Channel Islands, from December to March (Stewart and Huber, 1993; Stewart *et al.,* 1994); adults return between March and August to molt. The elephant seal breeding season peaks in late January to early February and molting peaks in late April to early May on SNI (Odell, 1974; Stewart and Yochem, 1984). After they spend time at sea to feed, females and juveniles haul out between March and May, with peak occurrences in April. Adult males tend to haul out and molt between June and August, with peak numbers in July.

In the late 1980s, elephant seals began to use west Daytona Beach (outside of the beach landing area) as a pupping area and have gradually moved eastward along the beach over the years. In 1988, 144 elephant seal pups were born at the west end of Daytona Beach. This number has increased steadily since then, reaching a total of 1,000 pups born at Daytona Beach in 1995 (Lowry *et al.,* 1996).

Daytona Beach had a two year average, from 2005 and 2010, of 1,787 elephant seals. Coast Guard Beach had an average of 1,895 elephant seals from the same two years (Lowry Unpublished Data). The average total of elephant seals for SNI from 2005 and 2010 was 14,750 (Lowry Unpublished Data). These numbers represent peak season counts and as such, are an overestimate for the proposed fall operations. Additionally, the Lowry survey counts were conducted over a larger area than the proposed action area at both Daytona and Coast Guard Beach (Areas ''C'' and ''Q'' in Figure 3 in the IHA application).

This species is not listed under the ESA and is not considered depleted under the MMPA. Based on trends in pup counts, northern elephant seal colonies were continuing to grow in California through 2005 (Carretta *et al.,* 2013).

California Sea Lion

The California sea lion is the most common pinniped at SNI. They haul out at many sites along southern and western SNI, including Daytona Beach and Coast Guard Beach. They haul out on SNI beaches to mate and pup beginning in late May and continuing through July. Females nurse their pups for 8 months, alternating between nursing the pups on land and foraging at sea. During the molting period, they haul out in September, and smaller numbers of females and juveniles haul out intermittently throughout the year.

The SNI population has ranged from 43,000 to 57,000 individuals since 2001. Pup production between 2003 and 2008 ranged from 25,000 to 29,000 (U.S. Navy, 2010). Large numbers of sea lions haul out and pup 0.5 mi west of the barge landing site at Daytona Beach (U.S. Navy, 2002). Mixed age groups intermittently haul out in the vicinity of the Daytona Beach barge landing area throughout the year, and bachelor bulls haul out at the barge landing site during June and July (Smith, 2005). In 2002, the number of California sea lions on Daytona Beach was estimated to be about 500 (U.S. Navy, 2002).

SNI had an average total of 51,797 California sea lions from 2004 to 2008 (Lowry Unpublished Data). Daytona Beach, between 2004 and 2008, had an average of 1,325 California sea lions while Coast Guard Beach had an average of 1,380 (Lowry Unpublished Data). These numbers represent peak season counts on Daytona and Coast Guard Beaches and as such, are an overestimate for the proposed fall operations. Additionally, the survey counts were conducted over a larger area than the proposed action area at both Daytona and Coast Guard Beach (see Figure 3 in the IHA application).

This species is not listed under the ESA and is not considered depleted under the MMPA. Based on trends in pup counts from non-El Nino years from 1975–2005, the population appears to be increasing.

Pacific Harbor Seal

Most harbor seals on SNI haul out at several specific, traditionally used sandy, cobble, and gravel beaches. Harbor seals are very rare at the barge landing area at Daytona Beach (Smith, 2005). However, West Coast Guard Beach is now the largest regularly used haul out on SNI (G. Smith, personal communication). Peak counts on SNI are about 450 seals, representing about 2 percent of the California stock.

Harbor seal haul out sites are distributed along mainland California and on off-shore islands, including the Channel Islands. Pupping occurs on beaches from late February through April on SNI, with nursing of pups extending into May. Harbor seals are abundant in late May and early June while they are molting and are least abundant in winter (Stewart and Yochem, 1984). For the years 2004, 2007 and 2009, Daytona Beach had an average of 69 harbor seals and Coast Guard Beach had an average of 201 (Lowry Unpublished Data). The average total for SNI for 2004, 2007 and 2009 was 800 harbor seals (Lowry Unpublished Data). These numbers represent peak season counts and as such, are an overestimate for the proposed fall operations. Additionally, the survey counts were conducted over a larger area than the proposed action area at both Daytona and Coast Guard Beach (see Figure 3 in the IHA application).

This species is not listed under the ESA and is not considered depleted under the MMPA. Counts of harbor seals in California increased from 1981

to 2004, and the population on the Channel Islands seems to have stabilized (Carretta *et al.,* 2013).

Potential Effects of the Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (e.g., barge beach landings, offloading, and barge removal) have been observed to or are thought to impact marine mammals. This section may include a discussion of known effects that do not rise to the level of an MMPA take (for example, with acoustics, we may include a discussion of studies that showed animals not reacting at all to sound or exhibiting barely measurable avoidance). The discussion may also include reactions that we consider to rise to the level of a take and those that we do not consider to rise to the level of a take. This section is intended as a background of potential effects and does not consider either the specific manner in which this activity will be carried out or the mitigation that will be implemented or how either of those will shape the anticipated impacts from this specific activity. The ''Estimated Take by Incidental Harassment'' section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis'' section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the ''Estimated Take by Incidental Harassment'' section, the ''Proposed Mitigation'' section, and the ''Anticipated Effects on Marine Mammal Habitat'' section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

The majority of impacts are likely to occur from the presence of personnel and equipment during the proposed activities. Barge beach landings and associated construction could affect pinnipeds hauled out at Daytona and Coast Guard beaches in two main ways:

1. Potential displacement of haul out areas at the barge landing site; and
2. Potential impacts of sound associated with barge landing and construction.

The Navy historically has had to displace pinnipeds from Daytona Beach and Coast Guard Beach during past barge landings and during construction of the pier at Daytona Beach (in 2005), and during repairs of the water system at Coast Guard Beach (in 2005 and 2006). Pinniped populations at Daytona Beach increased dramatically during historical barge beach landings (Smith, 2005).

According to pinniped displacement reports from 2003 to 2006, individual marine mammals hauling out on Daytona Beach during barge beach landings and pier construction appeared temporarily affected by the associated sound and presence of humans and equipment. The steady increase of pinniped populations at Daytona Beach throughout the history of barge beach landings before construction of the pier and during construction of the pier, suggests that the animals are not adversely affected by these activities. Like at Daytona Beach, marine mammals hauling out on Coast Guard Beach during repairs of the water system did not appear to be affected by the associated sound and presence of humans and equipment. Typical responses to displacement included increased alertness, raising of the head, and movement laterally along the beach or in the direction of the water (2006 displacement letter from Grace Smith to Rod McInnis/NMFS). The continued use of Coast Guard Beach by elephant seals and sea lions suggests that the pinniped populations were not adversely affected by these activities. The barge landings are not expected to affect pups or pinniped breeding behavior because beach landings would only take place from August 1 to November 30, outside the breeding season.

It may be necessary, for authorized biologists to move pinnipeds, if present, before the barge performs a beach landing on SNI. While barges transfer material off-shore, it is not anticipated that pinnipeds will exhibit startle responses or result in stampedes, as barges may be visible but are far enough off-shore to not cause a behavioral reaction.

It is anticipated that marine mammals will move to other available beaches and haulouts on SNI, away from the barge beach landings at Daytona or Coast Guard beaches. It is unlikely that pinnipeds will abandon these haulouts permanently, as noted by the earlier presented information.

Acoustic impacts, such as hearing impairment are not anticipated, as equipment is located far enough away from pinnipeds, sound levels will not occur at injurious levels.

Anticipated Effects on Marine Mammal Habitat

No critical habitat exists in the area of the proposed activities. During the period of the proposed activity, marine mammals may use various haul-outs around the barge landings and around SNI as places to rest and molt. The pinnipeds do not feed when hauled out. CA sea lions and elephant seals displaced into water usually move down-beach and haul out farther away from activity, while harbor seals will most likely stay in the water (G. Smith, personal communication). Therefore it is not expected that the barge activities will have any impact on the food or feeding success of the marine mammals. Although breeding occurs on SNI, the project dates have been planned to avoid the breeding/pupping season.

The sandy bottom would be disturbed offshore when the shipping barge dropped anchors and when the tender barge landed on the beach. Contact with the seafloor would temporarily increase turbidity, but no long-term adverse effects would result. Turbidity events would be limited to the duration of barge landing and offload.

The Navy anticipates and NMFS agrees that there will be no loss or permanent modification of the habitat used by marine mammal populations that haul-out in the barge landing areas. Temporary sand ramps would be constructed at Daytona and Coast Guard beaches to allow for transfer of material from the barge to dump trucks on the beach. Additionally, two tractors would be positioned on either side of the landing area before the tender barge arrives to provide stable anchorage for the tender barge. The area of the temporary sand ramps would be re-shaped on completion of each shipping barge offload, at the end of the 5 day period. Disturbance to marine mammal habitat would be only temporary. Because impacts are anticipated to be temporary, such that conditions will return to pre-activity condition in a short amount of time, and food sources will not be impacted, the proposed activity is not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Proposed Mitigation

In order to issue an incidental take authorization (ITA) under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant). Later in this document in the ''Proposed Incidental Harassment

Authorization'' section, NMFS lays out the proposed conditions for review, as they would appear in the final IHA (if issued).

Navy Proposed Mitigation Measures

In the IHA application, the Navy proposed a variety of measures, which are designed to reduce the level of disturbance for marine mammals that might be hauled out near the proposed barge landing sites. Additionally, all operations will be coordinated with the NBVC Point Mugu Environmental Division. The proposed mitigation measures include:

• All construction activity will take place within the proposed action footprint. Contractors will be provided with maps showing the centerlines and limits of surveys that were used for the environmental analyses in the final EA prepared by the Navy for this project (U.S. Navy, 2012) and informed that construction activity shall be confined to those corridors. Stakes will be used to delineate heavy equipment work and driving zones. Maps will include the locations of U.S. Army Corps of Engineers jurisdictional waters.

• All construction personnel must attend a mandatory environmental briefing at the start of the work day for work to be performed in sensitive habitats, and personnel attendance must be documented. For work in non-sensitive habitats, environmental briefings will occur weekly or as needed. Federal regulations regarding protected biological species must be emphasized, along with the importance of honoring environmental closure areas. The Environmental briefing would be given by Naval Facilities Engineering Command (NAVFAC) Southwest and NBVC personnel or the project biologist before work begins. If the training is given by the project biologist, then NAVFAC Southwest or NBVC staff would brief the project biologist, and the biologist would brief the crew on the resources and avoidance and compensation measures involved in the project. Environmental training will include a description of sensitive species and habitats potentially on or near the project site, and the surrounding habitat; details on each species' habitat requirements; the protective measures to be implemented for each species; and the responsibilities of the project biologist and of those on site to protect biological resources. The training will describe the requirements and boundaries of the project, the importance of complying with compensation measures, and the requirements for reporting non-compliance and any resolution methods. Training will provide information on and legal consequences of the potential effects of trash, trespassing, and harassing or harming designated sensitive habitat areas and species in or outside of the project footprint.

• Construction equipment will be inspected before mobilization to ensure no pinnipeds are under or near equipment.

• During barge landings and offloadings, the Navy biologist or qualified project biologist will displace pinnipeds from the landing site as necessary for the safety of the marine mammals and construction workers. Temporary barriers will be used, if necessary, to keep the displaced pinnipeds from re-entering the area. This effort will greatly minimize the potential for pinnipeds to be affected by project activities.

• No oil, fuel or chemicals will be allowed to discharged to waters of the state. Vessels will be equipped with spill kits and cleanup materials, and operators will be trained in responding to an accidental release of oil, fuel, or chemicals. Offloading equipment will be checked for leaks at the start of beach grading and aggregate offloading each day.

• Measures will be taken to prevent spillage of aggregate during the barge to barge transfer process. Measures may include but are not limited to, the use of a tarp or other barrier between the two barges, to capture spillage.

NMFS Proposed Mitigation Measures

In addition to the mitigation measures proposed by the Navy in the IHA application, NMFS proposes to include the following mitigation measures:

• Displacement must be conducted in such a way as to avoid stampedes. Approach of pinnipeds must be conducted gradually.

• Displacement or flushing of pinnipeds should be avoided, whenever possible, if dependent pups are present.

• The Navy will suspend activities immediately if an injured marine mammal is found in the vicinity of the proposed activity area and the proposed activities could aggravate its condition further. The incident must be reported to NMFS immediately.

Mitigation Conclusions

NMFS has carefully evaluated the Navy's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

• The manner in which, and the degree to which, the successful implementation of the measures are expected to minimize adverse impacts to marine mammals;

• The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and

• The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

3. A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing the severity of harassment takes only).

5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammals

species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. The Navy submitted a marine mammal monitoring plan as part of the IHA application. It can be found in Sections X and XII of the application. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

1. An increase in the probability of detecting marine mammals, both within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general to generate more data to contribute to the analyses mentioned below;

2. An increase in our understanding of how many marine mammals are likely to be exposed to levels of active seismic airguns that we associate with specific adverse effects, such as behavioral harassment, TTS, or PTS;

3. An increase in our understanding of how marine mammals respond to active seismic airguns or other stimuli expected to result in take and how anticipated adverse effects on individuals (in different ways and to varying degrees) may impact the population, species, or stock (specifically through effects on annual rates of recruitment or survival) through any of the following methods:

- Behavioral observations in the presence of active seismic operations compared to observations in the absence of active seismic airguns (need to be able to accurately predict received level and report bathymetric conditions, distance from source, and other pertinent information);
- Physiological measurements in the presence of active seismic airgun operations compared to observations in the absence of seismic airgun operations (need to be able to accurately predict received level and report bathymetric conditions, distance from source, and other pertinent information); and
- Distribution and/or abundance comparisons in times or areas with concentrated active seismic airgun operations versus times or areas without active airgun operations.

4. An increased knowledge of the affected species; and

5. An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

Proposed Monitoring Measures

The Navy biologist will monitor pinniped reactions to beach barge landings to ensure their protection and project compliance with the MMPA, and to ensure no Level A take occurs. The project biologist will monitor heavy equipment operation on the beach, as needed, to ensure compliance with compensation measures and will keep the project engineer, NAVFAC Southwest, and NBVC informed about construction that may threaten significant biological resources. The project biologist will record activities daily and provide electronic versions of biological monitoring reports at least weekly to NAVFAC Southwest and NBVC. The project biologist will be available to monitor construction activities to ensure compliance with sensitive biological resource avoidance and minimization measures, including implementation of specific measures for protection of marine mammals. The biologist will: (1) Ensure impacts on sensitive resources are minimized, (2) educate workers about sensitive habitats and how to implement avoidance and minimization measures, and (3) attend road repair-related meetings as needed.

Additionally, the Navy will implement the following three objectives from the 2010 Integrated Natural Resources Management Plan for NVBC, San Nicolas Island, California (INRMP).

1. Continue to monitor marine mammal populations and evaluate interactions related to island activities.

2. Monitor and protect island-wide pinniped breeding and haul-out sites.

3. Maintain adaptive management strategies to address complex issues related to marine mammal resource conflicts and occurrence.

More information regarding the INRMP and these monitoring goals can be found in the Navy's IHA application (see **ADDRESSES**).

Reporting Measures

A draft final report must be submitted to NMFS Office of Protected Resources within 90 days after the conclusion of the project. The report will include a summary of the information gathered pursuant to the monitoring requirements set forth in the IHA. The report must also summarize the results of the activities, marine mammal behavioral observations, and the estimated number of marine mammal takes. A final report must be submitted to the Director of the NMFS Office of Protected Resources and to the NMFS West Coast Regional Administrator within 30 days after receiving comments from NMFS on the draft final report. If no comments are received from NMFS, the draft final report will be considered to be the final report.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed roads and airfield repairs project. The barge landing and materials offload could temporarily displace marine mammals from their onshore haulouts, resulting in their movement into the water or down-beach. During barge landings, marine mammals may avoid the proposed project area and haul out at other beach areas.

The Navy requests authorization to take three marine mammal species by Level B (behavioral) harassment. These three marine mammal species are: Pacific harbor seal; California sea lion; and northern elephant seal.

Navy biologists conducted surveys at Daytona and Coast Guard beaches in October and November 2011 to count pinniped presence on SNI. These results have been used to help estimate the numbers of animals that may be taken by harassment during the proposed roads and airfield repairs project. Tables 3 through 5 in this document (and Tables 2 through 4 in the IHA application) outline the data collected during these surveys.

TABLE 3—FALL 2011 SURVEY RESULTS OF ELEPHANT SEALS

Survey date, 2011	Coast Guard Beach			Daytona Beach		
	East/brine pond	Coast Guard Beach	Former borrow pit	West	East of pier	West of pier
Oct 20	N/S	N/S	0	N/S	N/S	N/S
Oct 25	N/S	N/S	2 subadults	N/S	0	3 subadults
Oct 27	23 juveniles 2 females	0	2 juveniles 2 females	N/S	1 juvenile	0
Nov 1	0	N/S	1 individual	~60 mixed pinnipeds.	0	0
Nov 3	N/S	N/S	2 subadults	N/S	0	0
Nov 7	N/S	N/S	10 individuals	N/S	0	0
Nov 8	N/S	0	2 individuals	N/S	0	0

Notes: N/S Not surveyed

TABLE 4—FALL 2011 SURVEY RESULTS OF CALIFORNIA SEA LIONS

Survey date, 2011	Coast Guard Beach			Daytona Beach		
	East/brine pond	Coast Guard Beach	Former borrow pit	West	East of pier	West of pier
Oct 20	N/S	N/S	0	N/S	N/S	N/S
Oct 25	N/S	N/S	0	N/S	0	1 juvenile
Oct 27	1 female	1 juvenile	1 juvenile	N/S	0	0
Nov 1	0	N/S	0	~60 mixed pinnipeds.	0	0
Nov 3	N/S	N/S	0	N/S	0	1 subadult male
Nov 7	N/S	N/S	40 individuals	N/S	0	0
Nov 8	N/S	0	30 individuals	N/S	0	0

Notes: N/S Not surveyed

TABLE 5—FALL 2011 SURVEY RESULTS OF HARBOR SEALS

Survey date, 2011	Coast Guard Beach			Daytona Beach		
	East/brine pond	Coast Guard Beach	Former borrow pit	West	East of pier	West of pier
Oct 20	N/S	N/S	0	N/S	N/S	N/S
Oct 25	N/S	N/S	0	N/S	0	0
Oct 27	0	0	0	N/S	0	0
Nov 1	0	N/S	0	~60 mixed pinnipeds.	0	22 individuals
Nov 3	N/S	N/S	0	N/S	0	0
Nov 7	N/S	N/S	20 individuals	N/S	0	0
Nov 8	N/S	0	10 individuals	N/S	0	0

Notes: N/S Not surveyed

During the first year of this proposed project (August through November 2014), the Navy estimates that two shipments and beach preparations will occur. This will require a total of 10 days for site preparation and offloading operations. Based on the survey data collected in 2011 and the number of days of activities, the Navy estimates that no more than 50 harbor seal displacements will occur each day with the potential for take to be higher in August and lower in November when harbor seal numbers are very low on SNI (Stewart and Yochem, 1984). It is estimated that 75 sea lion displacements will occur each day, but haul-out numbers at Coast Guard Beach are intermittent in fall. It is estimated that 25 elephant seal displacements will occur each day with numbers increasing in October and November. Estimates include displacements during site preparation and off-loading. These numbers will likely include the displacement of returning individuals, such as elephant seals that will likely move back into the hazard area and have to be displaced multiple times. Table 6 presents the numbers of estimated takes by Level B (behavioral) harassment, the abundance of the stocks, the percentage of the stock potentially affected, and the population trend for each species or stock.

Common species name	Estimated take by level B harassment	Abundance of stock	Percentage of stock potentially affected	Population trend
Northern elephant seal	250	124,000	0.2	Increasing
California sea lion	750	296,750	0.3	Increasing

Common species name	Estimated take by level B harassment	Abundance of stock	Percentage of stock potentially affected	Population trend
Pacific harbor seal	500	30,196	1.7	Stable

Analysis and Preliminary Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (i.e., population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, feeding, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

These activities are anticipated to result in Level B harassment of hauled out pinnipeds in the form of displacement or behavioral disturbance. These activities are not anticipated to result in injury, serious injury, or mortality of any marine mammal species and none is proposed to be authorized. The proposed activities would only occur twice in a 4-month period, and each time, activities would only occur for 5 consecutive days. Therefore, over 4 months, activities would only occur for 10 days between August 1 and November 30.

None of the species for which take is proposed to be authorized are listed as threatened or endangered under the ESA or as depleted under the MMPA. No critical habitat exists for these species. While certain beaches and haulouts on SNI have been used for mating, breeding, and pupping, the project dates have been selected to avoid these sensitive time periods.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the Navy's proposed roads and airfield repairs project will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

Based on survey counts of marine mammals anticipated to be present at the two proposed activity sites and the number of times the proposed activity would occur, the Navy estimates that a total of 750 California sea lions, 500 Pacific harbor seals, and 250 northern elephant seals may be taken by Level B (behavioral) harassment during the course of the proposed activities. These estimates represent less than 1% of the California breeding stock of northern elephant seals and the U.S. stock of California sea lions and represents 1.7% of the California stock of Pacific harbor seals. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

No species listed under the ESA are expected to be affected by these activities. Therefore, NMFS has determined that a section 7 consultation under the ESA is not required.

National Environmental Policy Act (NEPA)

In June 2012, the Navy prepared a final EA for the *San Nicolas Island Roads and Airfield Repairs Project Naval Base Ventura County, California*. This EA is available on our Web site (see **ADDRESSES**). NMFS will review the Navy EA and either adopt it or prepare its own NEPA document before making a determination on the issuance of an IHA.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the Navy for the take of marine mammals incidental to conducting a road and airfield repairs project on SNI, California, from August 1 through November 30, 2014, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The proposed IHA language is provided next.

This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This IHA is valid from August 1 through November 30, 2014.

2. This IHA is valid only for the Navy's roads and airfield repairs project activities at Daytona and Coast Guard beaches, as described in the Navy's IHA application.

3. Species Authorized and Level of Take.

a. The incidental taking of marine mammals, by Level B harassment only, is limited to the following species:

i. Northern elephant seals—250.

ii. Pacific harbor seals—500.

iii. California sea lions—750.

b. The taking by injury (Level A harassment) serious injury, or death of any of the species listed in condition 3(a) or the taking of any kind of any other species of marine mammal is prohibited and may result in the modification, suspension or revocation of this IHA.

4. The taking of any marine mammal in a manner prohibited under this Authorization must be reported immediately to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, NMFS or her designee.

5. Mitigation and Monitoring Requirements: The Holder of this Authorization is required to implement the following mitigation and monitoring requirements when conducting the specified activities to achieve the least practicable impact on affected marine mammal species or stocks:

a. All construction activities will occur within the proposed action footprint, and contractors will be provided with maps delineating the

area. Stakes will be used to delineate heavy equipment work and driving zones.

b. All construction personnel must attend a mandatory environmental briefing at the start of the work day for work to be performed in pinniped haulout sites, and personnel attendance must be documented.

c. Construction equipment must be inspected before mobilization to ensure no pinnipeds are under or near equipment.

d. If displacement of pinnipeds is conducted, temporary barriers must be used, if necessary, to keep the displaced pinnipeds from re-entering the area during activities.

e. Displacement must be conducted in such a way as to avoid stampedes. Approach of pinnipeds must be conducted gradually.

f. Displacement or flushing of pinnipeds should be avoided, whenever possible, if dependent pups are present.

g. The Navy will suspend activities immediately if an injured marine mammal is found in the vicinity of the proposed activity area and the proposed activities could aggravate its condition further. The incident must be reported to NMFS immediately.

h. No oil, fuel or chemicals will be allowed to discharged to waters of the state. Vessels will be equipped with spill kits and cleanup materials, and operators will be trained in responding to an accidental release of oil, fuel, or chemicals. Offloading equipment will be checked for leaks at the start of beach grading and aggregate offloading each day.

i. Measures will be taken to prevent spillage of aggregate during the barge to barge transfer process. Measures may include but are not limited to, the use of a tarp or other barrier between the two barges, to capture spillage.

j. The Navy shall monitor marine mammal populations and evaluate interactions related to island activities.

k. The project biologist will record activities daily and provide electronic versions of biological monitoring reports at least weekly to NAVFAC Southwest and NBVC.

l. The Navy shall monitor and protect island-wide pinniped breeding and haul-out sites and abide by the conditions for this monitoring program contained in the INRMP.

m. The holder of this IHA is required to conduct monitoring of marine mammals present at the activity sites prior to, during, and for 30 minutes after the cessation of activities. Information to be recorded shall include the following: Species counts (with numbers of pups/juveniles); and Numbers of disturbances, by species and age, according to a three-point scale of intensity including (1) Head orientation in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, or changing from a lying to a sitting position and/or slight movement of less than 1 m; ''alert''; (2) Movements in response to or away from disturbance, typically over short distances (1–3 m) and including dramatic changes in direction or speed of locomotion for animals already in motion; ''movement''; and (3) All flushes to the water as well as lengthier retreats (> 3 m); ''flight''.

6. Reporting: The holder of this IHA is required to submit a draft monitoring report to NMFS Office of Protected Resources within 90 days after the conclusion of the activities. A final report shall be prepared and submitted within 30 days following resolution of any comments on the draft report from NMFS. This report must contain the informational elements described in condition 5(m), at minimum.

7. This IHA may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

8. A copy of this IHA must be in the possession of anyone operating under the authority of this Incidental Harassment Authorization.

9. Penalties and Permit Sanctions: Any person who violates any provision of this Incidental Harassment Authorization is subject to civil and criminal penalties, permit sanctions, and forfeiture as authorized under the MMPA.

Request for Public Comments

NMFS requests comments on our analysis, the draft authorization, and any other aspect of the Notice of Proposed IHA for the Navy's roads and airfield repairs project on SNI, California. Please include with your comments any supporting data or literature citations to help inform our final decision on the Navy's request for an MMPA authorization.

Dated: February 20, 2014.

Perry F. Gayaldo,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2014–04196 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office (USPTO).

Title: Patent Trial and Appeal Board (PTAB) Actions.

Form Number(s): None.

Agency Approval Number: 0651–0063.

Type of Request: Revision of a currently approved collection.

Burden: 858,683 hours annually.

Number of Respondents: 34,537 responses per year. The USPTO estimates that approximately 8,634 of these responses will be from small entities. The USPTO also estimates that 32,119 responses will be filed electronically.

Avg. Hours per Response: The USPTO estimates that it will take the public approximately 2 to 32 hours to complete the briefs, amendments, requests, and petitions in this collection, depending on the complexity of the request. This includes the time to gather the necessary information, prepare the brief, petition, and other papers, and submit the completed request to the USPTO. The USPTO assumes that, on balance, it takes the same amount of time to gather the necessary information, prepare the brief, petition, and other papers, and submit the completed request to the USPTO, whether the applicant submits it in paper form or electronically.

Needs and Uses: The Patent Trial and Appeal Board (PTAB or Board) is established by statute under 35 U.S.C. § 6. This statute directs that PTAB ''shall on written appeal of an applicant, review adverse decisions of examiners upon applications for patent and shall determine priority and patentability of invention in interferences.'' PTAB has the authority, under pre-AIA sections of the Patent Act, i.e., 35 U.S.C. §§ 134, 135, 306, and 315, to decide ex parte and inter partes appeals and interferences. The membership of the Board is established under 35 U.S.C. § 6. This collection permits applicants to prepare appeal and reply briefs which set forth the claims, issues, and arguments on appeal to the PTAB and permits applicants to file amendments to cancel pending, rejected claims that

they do not wish to be considered on appeal by the Board. Applicants may request that the PTAB reconsider its decision by filing a request for rehearing before the PTAB. Parties may also petition the Chief Administrative Patent Judge on matters pending before the Board. The PTAB uses the information to aid in rendering a decision on the claims, issues, and arguments submitted by the applicant, to determine which claims are on appeal, to decide whether to grant or deny a request for reconsideration of a decision, and to determine whether the necessary information has been provided to grant the petition. There are no forms associated with the items in this collection; however, they are governed by the rules in Part 41 and failure to comply with the appropriate rule may result in the dismissal of the appeal or denial of entry of the paper.

Affected Public: Individuals or households; businesses or other for-profits; non-profit institutions; and the Federal Government.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.*

Once submitted, the request will be publicly available in electronic format through the Information Collection Review page at *www.reginfo.gov.*

Paper copies can be obtained by:

• *Email: InformationCollection@uspto.gov.* Include ''0651–0063 copy request'' in the subject line of the message.

• *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before March 28, 2014 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Dated: February 20, 2014.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2014–04038 Filed 2–25–14; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Meeting of the Department of Defense Military Family Readiness Council (MFRC); Cancellation

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Notice; cancellation.

SUMMARY: On Friday, January 31, 2014 (79 FR 5385), the Department of Defense published a notice announcing a meeting of the Military Family Readiness Council (MFRC) that was to take place on Friday, February 28, 2014. The meeting of Friday, February 28, 2014 was cancelled.

Due to schedules conflicts the MFRC is unable to assemble a quorum of members for the previously scheduled meeting on February 28, 2014. Therefore, the Department of Defense is cancelling the previously scheduled meeting.

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Ms. Betsy Graham, Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. Telephones (571) 372–0880; (571) 372–0881 and/or email: OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil.*

SUPPLEMENTARY INFORMATION: Due to the circumstances beyond the control of the Designated Federal Officer, the Department of Defense must cancel the previously scheduled meeting of the Department of Defense Military Family Readiness Council on February 28, 2014. As a result, the Department of Defense is unable to provide appropriate notification as required by 41 CFR 102–3.150(a). Therefore, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Dated: February 21, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–04170 Filed 2–25–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2014–0002]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to add a new System of Records.

SUMMARY: The Department of the Army proposes to add a new system of records in its inventory of record systems subject to the Privacy Act of 1974, as amended. This system will provide commanders and personnel specialists with near real time accountability data for military, civilian, and contractor personnel in a deployed theater. The information collected establishes and maintains a central personnel records repository for personnel accountability, strength management reporting, and compliance with deployment health policies and readiness reporting.

DATES: Comments will be accepted on or before March 28, 2014. This proposed action will be effective on the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Jr., Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905 or by calling (703) 428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or the Defense Privacy and Civil Liberties Office Web site at *http://dpclo.defense.gov/.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was

submitted on February 21, 2014, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: February 21, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0715–9a G–1

SYSTEM NAME:

Deployed Theater Accountability System

SYSTEM LOCATION:

For location of systems, contact the Product Director, Army Human Resource System, 200 Stovall Street, Room 8N09, ATTN: SFAE–PS–IP–HR, Alexandria, VA 22332–6202.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Deployed Army military personnel (Active, Reserve, National Guard), DoD civilians, and DoD contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

DEPLOYED ARMY MILITARY:

Name, citizenship, race/ethnicity, gender, marital status, birth date, religious preference, DoD ID Number, Social Security Number (SSN), security clearance, deployment location information, and medical information as outlined in DoD Instruction 6490.03, Deployment Health.

DEPLOYED DOD CIVILIANS:

Name, citizenship, race/ethnicity, gender, marital status, birth date, religious preference, DoD ID Number, SSN, security clearance, deployment location information, and medical information as outlined in DoD Instruction 6490.03, Deployment Health.

DEPLOYED CONTRACTORS:

Name, citizenship, Letter of Authorization, Contract Number, Task Order Number, contractor identifier, DoD ID Number, Contracting Officer's Representative name, deployment location information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 1074, Medical Care and Tracking and Health Surveillance in the Theater of Operation; 10 U.S.C. 991, Management of deployments of members and measurement and data collection of unit operating and personnel tempo; 10 U.S.C. 482, Quarterly reports: personnel and unit readiness; 10 U.S.C. 165, Combatant commands: administration and support; 10 U.S.C. 166, Combatant commands: budget proposals; DoD Directive 1000.25, DoD Personnel Identity Protection (PIP) Program; DoD Directive 1400.31, DoD Civilian Work Force Contingency and Emergency Planning and Execution; DoD Instruction 1400.32, DoD Civilian Work Force Contingency and Emergency Planning Guidelines and Procedures; DoD Directive 1404.10, DoD Civilian Expeditionary Workforce; DoD Instruction 3020.41, Operational Contract Support; DoD Instruction 3020.50, Private Security Contractors (PSCs) Operating in Contingency Operations, Humanitarian or Peace Operations, or Other Military Operations or Exercises; DoD 6025.19, Medical Readiness; DoD Instruction 6490.03, Deployment Health; Chairman of the Joint Chiefs of Staff Manual 3150.13C, Joint Reporting Structure—Personnel Manual; Army Regulation 715–9, Operational Contract Support Planning and Management; and E.O. 9397 (SSN), as amended.

PURPOSE(S):

The Deployed Theater Accountability System (DTAS) is an Army system that provides commanders and personnel specialists with near real time accountability data for military, civilian, and contractor personnel in a deployed theater. The information collected establishes and maintains a central personnel records repository for personnel accountability, strength management reporting, and compliance with deployment health policies and readiness reporting.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD Blanket Routine Uses set forth at the beginning of the Army's compilation of systems of records notices may apply to this system.

This system of records contains individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18–R), issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18–R may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974, as amended, or mentioned in this system of records notice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Name, SSN (last four) or DoD ID number.

SAFEGUARDS:

DoD Components and approved users ensure that electronic records collected and used are maintained in controlled areas accessible only to authorized personnel. Physical security differs from site to site, but the automated records must be maintained in controlled areas accessible only by authorized personnel. Access to computerized data is restricted by use of common access cards (CACs) and is accessible only by users with an authorized account. The system and electronic backups are maintained in controlled facilities that employ physical restrictions and safeguards such as security guards, identification badges, key cards, and locks.

RETENTION AND DISPOSAL:

Permanent. Keep until individual's final deployment is terminated and then retire to the Army Electronic Archives (AEA). The AEA will transfer to the National Archives when the record is 25 years old.

SYSTEM MANAGER(S) AND ADDRESS:

Product Director, Army Human Resource System, 200 Stovall Street, Room 8N09, ATTN: SFAE–PS–IP–HR, Alexandria, VA 22332–6202.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to APM, Army Human Resource System, 200 Stovall Street, Room 8N09, ATTN: SFAE–PS–IP–HR, Alexandria, VA 22332–6202.

Requests should contain the individuals' full name, SSN (last four) or DoD ID number, current address, telephone number and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

IF EXECUTED OUTSIDE THE UNITED STATES:

'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United State of America that the foregoing is true and correct. Executed on (date). (Signature)'.

IF EXECUTED WITHIN THE UNITED STATES, ITS TERRITORIES, POSSESSIONS, OR COMMONWEALTHS:

'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to APM, Army Human Resource System, 200 Stovall Street, Room 8N09, ATTN: SFAE–PS–IP–HR, Alexandria, VA 22332–6202.

Requests should contain the individuals' full name, SSN (last four) or DoD ID number, current address, telephone number and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

IF EXECUTED OUTSIDE THE UNITED STATES:

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IF EXECUTED WITHIN THE UNITED STATES, ITS TERRITORIES, POSSESSIONS, OR COMMONWEALTHS:

'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Defense Enrollment Eligibility Reporting Systems (DEERS), Synchronized Predeployment and Operational Tracker Enterprise Suite (SPOT–ES), and Electronic Military Personnel Office (eMILPO) systems of records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2014–04150 Filed 2–25–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2013–ICCD–0153]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Teacher Incentive Fund Annual Performance Report

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before March 28, 2014.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2013–ICCD–0153 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Lakesha Davis, 202–205–9533.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Teacher Incentive Fund Annual Performance Report.

OMB Control Number: 1810–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, or Tribal Governments.

Total Estimated Number of Annual Responses: 92.

Total Estimated Number of Annual Burden Hours: 4,232.

Abstract: ED requests a customized annual performance report (APR) that goes beyond the standard APR ED Form 524B; in order to facilitate the collection of more standardized and comprehensive data to inform Government Performance and Results Act (GPRA) measures to improve the overall quality of data collection, and to increase the quality and quantity of data that can be used to inform policy decisions and report to Congress.

Dated: February 20, 2014.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2014–04050 Filed 2–25–14; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Committee on Foreign Medical Education and Accreditation

AGENCY: Office of Postsecondary Education, U.S. Department of Education, National Committee on Foreign Medical Education and Accreditation.

ACTION: The purpose of this notice is to announce the upcoming meeting of the National Committee on Foreign Medical Education and Accreditation (NCFMEA). Parts of this meeting will be

open to the public, and the public is invited to attend those portions.

Meeting Date and Place: The public meeting will be held on Tuesday, April 15, 2014, from 8:00 a.m. until approximately 5:30 p.m., at the U.S. Department of Education, Eighth Floor Conference Center, Office of Postsecondary Education, 1990 K Street NW., Washington, DC 20006. On Wednesday, April 16, 2014, the Committee will meet in Executive Session from 8:00 a.m. until approximately 2:00 p.m. This session will not be open to the public.

Function: The NCFMEA was established by the Secretary of Education under Section 102 of the Higher Education Act of 1965, as amended. The NCFMEA's responsibilities are to:

- Upon request of a foreign country, evaluate the standards of accreditation applied to medical schools in that country; and,
- Determine the comparability of those standards to standards for accreditation applied to United States medical schools.

Comparability of the applicable accreditation standards is an eligibility requirement for foreign medical schools to participate in the William D. Ford Federal Direct Student Loan Program, 20 U.S.C. 1087a et seq.

Meeting Agenda: The NCFMEA will review the standards of accreditation applied to medical schools by several foreign countries to determine whether those standards are comparable to the standards of accreditation applied to medical schools in the United States and/or reports previously requested of countries by the NCFMEA. Discussion of the standards of accreditation will be held in sessions open to the public. Discussions resulting in specific determinations of comparability are closed to the public in order that each country may be properly notified by the Department of the Committee's decision.

The countries which are scheduled to be discussed are Costa Rica, Grenada, India, Mexico, The Netherlands, Nevis, and Pakistan. The meeting agenda, as well as the staff analyses pertaining to the meeting will be posted on the Department of Education's Web site prior to the meeting at *http://www2.ed.gov/about/bdscomm/list/ncfmea.html.*

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice by April 4, 2014, although we will attempt to meet a request received after that date.

FOR FURTHER INFORMATION CONTACT: Carol Griffiths, Executive Director for the NCFMEA, U.S. Department of Education, 1990 K Street NW., Room 8073, Washington, DC 20006–8129, telephone: 202 219–7035; fax: 202 502–7874, or email: *Carol.Griffiths@ed.gov.*

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Brenda Dann-Messier,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 2014–04076 Filed 2–25–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

External Merit Review Meeting

AGENCY: Wind and Water Power Technologies, Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of External Peer Review meeting.

SUMMARY: The Wind Power Technologies Office within the U.S. Department of Energy's (DOE) Office of Energy Efficiency and Renewable Energy intends to hold an External Merit Review in Arlington, VA, on March 24–28, 2014. The External Review Panel will review current projects and provide feedback on technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of projects. The review panel will also assess projects' potential impact on the wind power industry and identify additional research initiatives and resources that might be required in the future. The event is open to the public based upon space availability.

DATES: DOE will hold the External Peer Review from Monday, March 24th, through Friday, March 28, 2014.

ADDRESSES: The public meeting will be held at the DoubleTree Crystal City, 300 Army Navy Drive, Arlington, VA 22203.

You may submit comments, identified by any of the following methods:

- *Email:* [*Mark.Higgins@ee.doe.gov*]. Include ''Wind Power Peer Review'' in the subject line of the message.
- *Postal Mail:* [Mark Higgins, EE–4W, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585] Due to the potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages respondents to submit comments electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Matthew Kalmuk, BCS, Incorporated, 1400 I (Eye) St. NW., Suite 510, Washington, DC 20005, *mkalmuk@bcs-hq.com.*

SUPPLEMENTARY INFORMATION:

Background

The U.S. Department of Energy's (DOE) Wind and Water Power Technologies is committed to developing and deploying a portfolio of innovative technologies for clean, domestic power generation from land-based and offshore wind turbines. The Wind and Water Power Technologies portfolio is aimed at producing the next generation of wind power technologies and jump-starting private sector innovation that is critical to the country's long-term economic growth, energy security, and international competitiveness. By executing objective, comprehensive Peer Reviews, the Wind and Water Power Technologies Office ensures that its portfolio of project addresses industry needs and impacts the long-term development and deployment of wind power technologies in the United States.

Public Participation

The event is open to the public based upon space availability. DOE will also accept public comments as described in **ADDRESSES** for purposes of developing the Wind Power Program portfolio, but will not respond individually to comments received.

Participants at the External Merit Review should limit information and comments to those based on personal

experience, individual advice, information, or facts regarding this topic. It is not the object of this session to obtain any group position or consensus from the meeting participants. To most effectively use the limited time, please refrain from passing judgment on another participant's recommendations or advice, and instead, concentrate on your individual experiences.

Following the meeting, a summary will be compiled by DOE and posted for public comment. For those interested in providing additional public comment, the summary will be posted at *energy.gov/eere/wind/wind.*

Information on Services for Individuals With Disabilities

Individuals requiring special accommodations at the meeting, please contact Mark Higgins no later than the close of business on March 21, 2014.

Issued in Washington, DC, on February 20, 2014.

Jose Zayas,

Director, Wind and Water Power Technologies Office, U.S. Department of Energy.

[FR Doc. 2014–04156 Filed 2–25–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–539–001.
Applicants: Appalachian Power Company, American Electric Power Service Corporation, PJM Interconnection, L.L.C.
Description: Appalachian Power Co. submits Compliance filing per 1/16/2014 Order in ER13–539 to be effective 7/9/2013.
Filed Date: 2/18/14.
Accession Number: 20140218–5150.
Comments Due: 5 p.m. ET 3/11/14.

Docket Numbers: ER14–1330–000.
Applicants: Duke Energy Progress, Inc.
Description: OATT NCEMC Power Supply Agreement RS No. 182 to be effective 4/19/2014.
Filed Date: 2/18/14.
Accession Number: 20140218–5065.
Comments Due: 5 p.m. ET 3/11/14.

Docket Numbers: ER14–1331–000.
Applicants: Southern California Edison Company.
Description: Unexecuted SGIA and Distribution Service Agreement with SEPV Mission Creek, LLC to be effective 4/20/2014.
Filed Date: 2/18/14.
Accession Number: 20140218–5147.
Comments Due: 5 p.m. ET 3/11/14.

Docket Numbers: ER14–1332–000.
Applicants: DATC Path 15, LLC.
Description: Revised Appendix I in TO Tariff Updating TRR to be effective 4/20/2014.
Filed Date: 2/18/14.
Accession Number: 20140218–5199.
Comments Due: 5 p.m. ET 3/11/14.

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: February 18, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–04048 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2609–007; ER10–2604–005; ER10–2603–005; ER10–2602–008; ER10–2606–007.
Applicants: Escanaba Paper Company, Luke Paper Company, Rumford Paper Company, NewPage Energy Services, LLC, Consolidated Water Power Company.
Description: Notice of Non-Material Change in Status of the NewPage MBR Companies.
Filed Date: 2/14/14.
Accession Number: 20140214–5232.
Comments Due: 5 p.m. ET 3/7/14.

Docket Numbers: ER10–2763–009; ER10–2759–003; ER10–2732–009; ER10–2736–009; ER10–2737–009; ER10–2741–009; ER10–2749–009; ER10–2752–009; ER12–2492–005; ER12–2493–005; ER12–2494–005; ER12–2495–005; ER12–2496–005; ER10–2733–009; ER10–2734–009; ER10–2631–003; ER13–815–001.
Applicants: Bangor Hydro Electric Company, Bridgeport Energy LLC, Emera Energy Services Inc., Emera Energy Services Subsidiary No. 1 LLC, Emera Energy Services Subsidiary No. 2 LLC, Emera Energy Services Subsidiary No. 3 LLC, Emera Energy Services Subsidiary No. 4 LLC, Emera Energy Services Subsidiary No. 5 LLC, Emera Energy Services Subsidiary No. 6 LLC, Emera Energy Services Subsidiary No. 7 LLC, Emera Energy Services Subsidiary No. 8 LLC, Emera Energy Services Subsidiary No. 9 LLC, Emera Energy Services Subsidiary No. 10 LLC, Emera Energy U.S. Subsidiary No. 1, Inc., Emera Energy U.S. Subsidiary No. 2, Inc., Rumford Power Inc., Tiverton Power LLC.
Description: Errata to December 30, 2013 Triennial Market Power Update for Northeast Region and Notice of Two Changes in Status of the Emera Entities.
Filed Date: 2/14/14.
Accession Number: 20140214–5233.
Comments Due: 5 p.m. ET 3/7/14.

Docket Numbers: ER14–225–002.
Applicants: New Brunswick Energy Marketing Corporation.
Description: Triennial Review Compliance Filing of New Brunswick Energy Marketing Corporation.
Filed Date: 2/14/14.
Accession Number: 20140214–5226.
Comments Due: 5 p.m. ET 4/15/14.

Docket Numbers: ER14–612–004.
Applicants: Skylar Energy LP.
Description: Notice of Non-Material Change in Status of Skylar Energy LP.
Filed Date: 2/14/14.
Accession Number: 20140214–5229.
Comments Due: 5 p.m. ET 3/7/14.

Docket Numbers: ER14–1014–000; ER14–1033–000; ER14–1034–000; ER14–1035–000; ER14–1036–000; ER14–1043–000; ER14–1044–000; ER14–1046–000; ER14–1047–000.
Applicants: Bridgeport Energy LLC.
Description: Supplement to January 17, 2014 Bridgeport Energy LLC, et. al. tariff filing.
Filed Date: 2/12/14.
Accession Number: 20140212–5156.
Comments Due: 5 p.m. ET 2/26/14.

Docket Numbers: ER14–1316–000.
Applicants: FirstEnergy Service Company, FirstEnergy Solutions Corp.
Description: FirstEnergy Service Company on behalf of FirstEnergy Solutions Corp. submits Notice of Cancellation of Annual Revenue

Requirement for Reactive Supply Service for the Seneca Pumped Storage Station.

Filed Date: 2/12/14.

Accession Number: 20140212–5085.

Comments Due: 5 p.m. ET 3/5/14.

Docket Numbers: ER14–1326–000.

Applicants: Entergy Louisiana, LLC.

Description: ELL–EGSL-Cleco Implementation Agmt 2–14–2014 to be effective 2/15/2014.

Filed Date: 2/14/14.

Accession Number: 20140214–5149.

Comments Due: 5 p.m. ET 3/7/14.

Docket Numbers: ER14–1327–000.

Applicants: PJM Interconnection, L.L.C.

Description: Original SA No. 3770 and Cancellation of SA No. 3283; Queue No. X1–037 to be effective 1/13/2014.

Filed Date: 2/14/14.

Accession Number: 20140214–5159.

Comments Due: 5 p.m. ET 3/7/14.

Docket Numbers: ER14–1328–000.

Applicants: Entergy Louisiana, LLC.

Description: ELL Cancellation of SA 2–14–2014 to be effective 2/14/2019.

Filed Date: 2/14/14.

Accession Number: 20140214–5175.

Comments Due: 5 p.m. ET 3/7/14.

Docket Numbers: ER14–1329–000.

Applicants: Entergy Gulf States Louisiana, L.L.C.

Description: EGSL Cancellation of SA 2–14–2014 to be effective 2/14/2019.

Filed Date: 2/14/14.

Accession Number: 20140214–5176.

Comments Due: 5 p.m. ET 3/7/14.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–24–000.

Applicants: Southwestern Electric Power Company.

Description: Amendment to January 27, 2013 Application of Southwestern Electric Power Company under Section 204 of the Federal Power Act for Authorization to Issue Securities.

Filed Date: 2/12/14.

Accession Number: 20140212–5157.

Comments Due: 5 p.m. ET 2/24/14.

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: February 18, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–04049 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–30–000]

Midcontinent Independent System Operator, Inc. v. Southwest Power Pool; Notice of Complaint

Take notice that on February 18, 2014, pursuant to sections 206 and 212 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and 385.212 and sections 206 and 306 of the Federal Power Act, 16 USC 824(e) and 825(e), Midcontinent Independent System Operator, Inc. (MISO or Complainant) filed a formal complaint against Southwest Power Pool (SPP or Respondent) alleging that the Respondent is violating its Open Access Transmission Tariff (Tariff) and the MISO–SPP Joint Operating Agreement by invoicing Complainant for certain transmission service. Among other things, Complainant requests the Commission issue an order directing SPP to cease issuing invoices to MISO for such service, including unreserved use penalties, under the SPP's Tariff.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive 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.

Comment Date: 5:00 p.m. Eastern Time on March 10, 2014.

Dated: February 19, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04043 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. PF14–1–000; PF14–2–000; PF14–6–000]

Sabal Trail Transmission, LLC, Florida Southeast Connection, LLC, Transcontinental Gas Pipe Line Company, LLC, Notice of Intent To Prepare an Environmental Impact Statement for the Planned Southeast Market Pipelines Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Meetings

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) that discusses the environmental impacts of the planned Southeast Market Pipelines (SMP) Project. The SMP Project is comprised of three separate, but connected, natural gas transmission pipeline projects: Sabal Trail Transmission, LLC's (Sabal Trail's) Sabal Trail Project in Alabama, Georgia, and Florida; Florida Southeast Connection, LLC's (FSC's) Florida Southeast Connection Project (FSC Project) in Florida; and Transcontinental Gas Pipe Line Company, LLC's (Transco's) Hillabee

Expansion Project in Alabama. The environmental impacts of all three projects will be considered in one EIS, which will be used by the Commission in its decisionmaking process to determine whether the SMP Project is in the public convenience and necessity.

This notice, which is being sent to the Commission's current environmental mailing list for the SMP Project, announces the opening of the scoping process that will be used to gather input about the SMP Project from the public and other interested stakeholders. State and local government representatives should notify their constituents about this process and encourage them to comment on their areas of concern. Scoping comments will help the Commission's staff determine what issues will need to be evaluated in the EIS. Please note that the scoping period will close on April 20, 2014.

Comments about the SMP Project may be submitted in written form or verbally. The Public Participation section of this notice describes how to submit written comments. Verbal comments can be given at the public scoping meetings to be held in the SMP Project area as scheduled below.

Date and time	Location
Monday, March 3, 2014, 6:00 p.m.	Hilton Garden Inn Albany, 101 South Front Street, Albany, GA 31701, (229) 888–1590.
Tuesday, March 4, 2014, 6:00 p.m.	Holiday Inn Valdosta Conference Center, 1805 West Hill Avenue, Valdosta, GA 31601, (229) 244–1111.
Wednesday, March 5, 2014, 6:00 p.m.	Moultrie Technical Facility Building A, Veterans Parkway Conference Center, 800 Veterans Parkway North, Moultrie, GA 31788, (229) 217–4185.
Monday, March 10, 2014, 6:00 p.m.	Russell County High School, 4716 Old Seale Highway, Seale, AL 36875, (334) 855–4378.
Tuesday, March 11, 2014, 6:00 p.m.	Central Alabama Community College, Betty Carol Graham Technology Center, 1675 Cherokee Road, Alexander City, AL 35010, (256) 234–6346.
Wednesday, March 12, 2014, 6:00 p.m.	Butler Civic Center, 108 North Academy Avenue, Butler, AL 36904, (205) 459–3795.
Tuesday, March 18, 2014, 6:00 p.m.	Lake Wales Art Center, 1099 East Florida 60, Lake Wales, FL 33853, (863) 676–8426.
Wednesday, March 19, 2014, 6:00 p.m.	Okeechobee High School, 2800 Highway 441 North, Okeechobee, FL 34972, (863) 462–5025.
Thursday, March 20, 2014, 6:00 p.m.	Kissimmee Civic Center, 201 East Dakin Avenue, Kissimmee, FL 34741, (407) 935–1412.
Monday, March 24, 2014, 6:00 p.m.	Live Oak City Hall, 101 White Avenue Southeast, Live Oak, FL 32064, (386) 362–2276.
Tuesday, March 25, 2014, 6:00 p.m.	Bell High School, 930 South Main Street, Bell, FL 32619, (352) 463–3232.
Wednesday, March 26, 2014, 6:00 p.m.	Rainbow Springs Country Club, 19330 Southwest 83rd Place Road, Dunnellon, FL 34432, (352) 489–3348.
Thursday, March 27, 2014, 6:00 p.m.	Citrus Tower, 141 North Highway 27, Clermont, FL 34711, (352) 394–4061.

The purpose of these scoping meetings is to provide the public an opportunity to learn more about the Commission's environmental review process, and to verbally comment on the SMP Project. Representatives from Sabal Trail, FSC, and Transco, as applicable, will be present one hour prior to each scoping meeting to answer questions about their respective SMP Project component. Affected landowners and other interested parties are encouraged to attend the scoping meetings and to give their comments on the issues they believe should be addressed in the EIS. A transcript of each meeting will be added to the Commission's administrative record to ensure that your comments are accurately recorded.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned pipeline facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the SMP Project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, a condemnation proceeding could be initiated where compensation would be determined in accordance with state law.

The ''For Citizens'' section of the FERC Web site (*www.ferc.gov*) provides more information about the FERC and the environmental review process. This section also includes information about getting involved in FERC jurisdictional projects, and a citizens' guide entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need to Know?'' This guide addresses a number of frequently asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Summary of the Planned Project

Sabal Trail, FSC, and Transco plan to construct and operate over 650 miles of interstate natural gas transmission pipeline and associated facilities in Alabama, Georgia, and Florida. The Sabal Trail Project would connect with the Hillabee Expansion Project in Alabama, and the FSC Project in Florida. The general location of the SMP Project facilities is shown in Appendix 1. The facilities associated with each project component are described below.

Sabal Trail Project

Sabal Trail plans to construct and operate approximately 460 miles of 36-inch-diameter natural gas transmission pipeline beginning in Tallapoosa County, Alabama and ending in Osceola County, Florida. The new pipeline would cross Tallapoosa, Chambers, Lee, and Russell Counties, Alabama; Stewart, Webster, Terrell, Lee, Dougherty, Mitchell, Colquitt, Brooks, and Lowndes Counties, Georgia; and Hamilton, Madison, Suwannee, Gilchrist, Alachua, Levy, Marion, Sumter, Lake, Polk, and Osceola Counties, Florida.

Sabal Trail also plans to construct and operate approximately 14 miles of 36-inch-diameter natural gas transmission pipeline in Osceola and Orange Counties, Florida (Hunters Creek Line) and approximately 24 miles of 24-inch-diameter natural gas transmission pipeline in Marion and Citrus Counties, Florida (Citrus County Line).

In addition to the planned pipelines, Sabal Trail would construct and operate five new compressor stations. These compressor stations would be located in Tallapoosa County, Alabama; Dougherty County, Georgia; and Suwannee, Marion, and Osceola Counties, Florida. Sabal Trail would also lease the capacity of Transco's Hillabee Expansion Project.

Lastly, Sabal Trail plans to construct a natural gas hub in Osceola County, Florida. A natural gas hub provides customers with receipt/delivery access to two or more interstate pipeline systems, provides transportation between these points, and offers administrative services that facilitate the movement and/or transfer of gas ownership.

The Sabal Trail Project would have an initial capacity of 800,000 dekatherms per day (Dth/d) with an initial in-service date of May 1, 2017. Through a series of phased compressor station expansions, the capacity of the Sabal Trail Project would increase to 1.1 million Dth/d by 2021.

FSC Project

FSC plans to construct and operate approximately 126 miles of up to 36-inch-diameter natural gas transmission pipeline beginning in Osceola County, Florida and ending at Florida Power & Light Company's Martin Clean Energy Center in Martin County, Florida. The new pipeline would cross Polk, Osceola, Okeechobee, St. Lucie, and Martin Counties, Florida.

The FSC Project would have an initial capacity of at least 600,000 Dth/d beginning on May 1, 2017.

Hillabee Expansion Project

Transco plans to construct and operate approximately 43.6 miles of 42- and 48-inch-diameter natural gas transmission pipeline in eight loop [1] segments in Choctaw, Autauga, Chilton, Coosa, and Tallapoosa Counties, Alabama. The Hillabee Expansion Project would also include one new compressor station in Choctaw County, Alabama and additional compression/modifications at three existing compressor stations in Dallas, Chilton, and Coosa Counties, Alabama.

Construction of the Hillabee Expansion Project would occur in phases resulting in an initial capacity of approximately 800,000 Dth/d to be leased to Sabal Trail on May 1, 2017, increasing to approximately 1.1 million Dth/d by 2021. The first phase of the project would involve compressor station modifications and the construction of pipeline in Autauga, Chilton, Choctaw, Coosa, Dallas, and Tallapoosa Counties, Alabama.

Land Requirements for Construction

Construction of the planned SMP Project facilities would disturb about 13,670 acres of land. The typical construction right-of-way for pipeline facilities would vary between 100 and 110 feet wide in uplands and 75 feet wide in wetlands, with additional workspace needed in some locations due to site-specific conditions and activities. Following construction, approximately 4,320 acres of land would be retained for permanent operation of the facilities. Land affected by construction but not required for operation would generally be allowed to revert to former uses.

The EIS Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity under Section 7 of the Natural Gas Act. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This discovery process is commonly referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to be addressed in the EIS. All comments received will be considered during the preparation of the EIS, and addressed as appropriate.

In the EIS we will discuss impacts that could occur as a result of the construction and operation of the planned SMP Project under these general headings:

- geology and soils;
- water resources, including surface waters and groundwater;
- wetlands;
- vegetation, fisheries, and wildlife,
- threatened and endangered species;
- land use;
- socioeconomics;
- cultural resources;
- air quality and noise;
- public safety and reliability; and
- cumulative impacts.

We will also evaluate alternatives to the SMP Project, project components, pipeline routes, and aboveground facility locations; and make recommendations on how to avoid or minimize impacts on the various resource areas.

Although no formal applications have been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact federal and state agencies to discuss their involvement in the scoping process and the preparation of the EIS.

The EIS will present our independent analysis of the issues. We will publish and distribute a draft EIS for public comment. After the comment period, we will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section below.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to the SMP Project to formally cooperate with us in the preparation of the EIS.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. Currently, the U.S. Army Corps of Engineers (COE) has expressed its intent to participate as a cooperating agency in the preparation of the EIS to satisfy its NEPA responsibilities related to this project. The COE has jurisdictional authority pursuant to Section 404 of the Clean Water Act, which governs the discharge of dredged or fill material into waters of the United States, and Section 10 of the Rivers and Harbors Act, which regulates any work or structures that potentially affect the navigability of a waterway.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the Alabama, Georgia, and Florida State Historic Preservation Offices (SHPOs), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the SMP Project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the SMP Project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, meter stations, and access roads). Our EIS for the SMP Project will document

[1] A loop is a segment of pipe that is usually installed adjacent to an existing pipeline and connected to it at both ends. The loop allows more gas to be moved through the system.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register for Historic Places.

our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

Based on our preliminary review of the project; information provided by Sabal Trail, FSC, and Transco; and public comments filed in the Commission's administrative record and submitted to staff at the applicant-sponsored open houses, we have identified several issues that we think deserve attention. This preliminary list of issues may change based on your comments and our ongoing environmental analysis. These issues are:

- purpose and need for the SMP Project;
- impacts of clearing forested areas and other vegetation;
- impacts on water resources including sensitive springs, groundwater, and wetlands;
- karst terrain;
- impacts on land use;
- environmental justice;
- the use of eminent domain to obtain project easements;
- impacts on property values, tourism, and recreational resources;
- cultural resources;
- compressor station noise;
- pipeline integrity and public safety; and
- alternatives and cumulative impacts.

Public Participation

You can make a difference by providing us with your comments about the SMP Project. Your comments should focus on the potential environmental impacts of the project, reasonable alternatives, and measures to avoid or lessen these environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are considered in a timely manner and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before April 20, 2014.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please refer to the appropriate project docket number (PF14–1–000 for the Sabal Trail Project; PF14–2–000 for the FSC Project; or PF14–6–000 for the Hillabee Expansion Project) with your submission. If your comments apply to all three projects, then list all three. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the *eComment* feature located on the Commission's Web site (*www.ferc.gov*) under the *Documents and Filings* heading. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can also file your comments electronically using the *eFiling* feature located on the Commission's Web site (*www.ferc.gov*) under the *Documents and Filings* heading. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing;'' or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who has submitted comments on the SMP Project in the Commission's administrative record. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned SMP Project.

Copies of the draft EIS will be sent to the environmental mailing list for review and comment. If you would prefer to receive a paper copy of the EIS instead of the compact disc version or if you would like to remove your name from the mailing list, please return the attached Information Request (Appendix 2).

Becoming an Intervenor

Once the SMP Project proponents file applications with the Commission, you may want to become an ''intervenor,'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor can be found under the ''Getting Involved'' heading of the ''For Citizens'' section on the FERC Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project.

Additional Information

Additional information about the SMP Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC Web site (*www.ferc.gov*) using the eLibrary. Click on the eLibrary link, click on ''General Search,'' and enter the docket number, excluding the last three digits (PF14–1, PF14–2, or PF14–6). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: February 18, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04046 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER14–1341–000]

Solea Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Solea Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is March 11, 2014.

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 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: February 19, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04044 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR14–21–000]

North Dakota Pipeline Company LLC; Notice of Petition for Declaratory Order

Take notice that on February 12, 2014, pursuant to Rule 207(a)(2) of the Commission's Rules of Practices and Procedure, 18 CFR 385.207(a)(2)(2014), North Dakota Pipeline Company LLC (''North Dakota Pipeline'') filed a petition requesting a declaratory order approving the general tariff rate and service structure, and apportionment principles for North Dakota Pipeline's revised Sandpiper Project to move Bakken crude to an interconnection with the Lakehead System at Superior, WI, as explained more fully in the petition.

Any person desiring to intervene or to protest in this proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive 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.

Comment Date: 5:00 p.m. Eastern time on March 14, 2014

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04045 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14512–000]

KC Pittsfield, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 18, 2013, KC Pittsfield, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Old Cow Creek Open-Channel Hydro Project (Old Cow Creek Project or project) to be located on Old Cow Creek, near Whitmore, California. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A diversion intake on Old Cow Creek located just above Pacific Gas & Electric Company's (PG&E) existing diversion; (2) a new 100-cubic foot per second canal that would run parallel to PG&E's existing 3-mile-long canal; (3) a powerhouse located adjacent to the existing PG&E powerhouse; (4) two 3-megawatt conventional hydroelectric turbines; and (5) appurtenant facilities. The estimated average generating capacity of the project would be 31 gigawatt hours.

Applicant Contact: Ms. Kelly Sackheim, KC Pittsfield, LLC, 5096

Cocoa Palm Way, Fair Oaks, CA 95628, Telephone (301) 401–5978

FERC Contact: Joseph Hassell; phone: (202) 502–8079.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov*, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14512–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14512) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: February 19, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04040 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14515–000]

Fall River Valley Community Service District; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 22, 2013, Fall River Valley Community Service District filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Old Cow Creek Open-Channel Hydro Project (Old Cow Creek Project or project) to be located on Old Cow Creek, near Whitmore, California. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A diversion intake on Old Cow Creek located just above Pacific Gas & Electric Company's (PG&E) existing diversion; (2) a new 100 cubic feet per second canal that would run parallel to PG&E's existing 3-mile long canal; (3) a powerhouse located adjacent to the existing PG&E powerhouse; (4) two 3 MW conventional hydroelectric turbines, and; (5) appurtenant facilities. The estimated average generating capacity of the project would be 31 gigawatt hours.

Applicant Contact: Mr. David Hall, Fall River Valley Community Service District, P.O. Box 427, Fall River Mills, CA 96208, Telephone (530) 336–5263.

FERC Contact: Joseph Hassell; phone: (202) 502–8079.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14515–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14515) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: February 19, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04041 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1888–030]

York Haven Power Company, LLC; Notice of Settlement Agreement

Take notice that the following settlement agreement has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement Agreement.

b. *Project No.:* P–1888–030.

c. *Date filed:* January 30, 2014.

d. *Applicant:* York Haven Power Company, LLC.

e. *Name of Project:* York Haven Hydroelectric Project.

f. *Location:* On the Susquehanna River, in Dauphin, Lancaster, and York Counties, Pennsylvania. The project does not occupy any federal lands.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602.

h. *Applicant Contact:* David R. David, York Haven Power Company, York Haven Hydro Station, P.O. Box 67, York Haven, PA 17370, at (717) 266–9475 or email at *DDavid@yorkhavenpower.com* and Dennis T. O'Donnell, Olympus Power, LLC, 67 Park Place East, Morristown, NJ 07960.

i. *FERC Contact:* Emily Carter, (202) 502–6512 or *emily.carter@ferc.gov.*

j. The York Haven Power Company, LLC (York Haven) filed the Settlement Agreement on behalf of itself, the U.S. Fish and Wildlife Service (FWS), Pennsylvania Fish and Boat Commission (PFBC), Maryland Department of Natural Resources (MDNR), and the Susquehanna River Basin Commission (SRBC). The purpose of the Settlement Agreement is to resolve among the signatories all issues associated with issuance of a new license for the project regarding upstream passage of American eels, downstream passage of post-spawning American shad, downstream passage of juvenile American shad, downstream passage of silver stage American eel, resident fish passage, flow management, water quality and debris management,

and endangered species and species of special concern. York Haven requests that the Commission find that the Settlement Agreement is in the public interest, accept the Settlement Agreement, and issue a new license for the York Haven Project that incorporates the license terms and conditions set forth in Section 3.0 of the Settlement Agreement without modification or condition.

k. A copy of the settlement agreement is available for review on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: February 19, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04039 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD14–6–000]

New York Independent System Operator, Inc.; Supplemental Notice of Technical Conference

As announced in the Notice issued on January 28, 2014, the Federal Energy Regulatory Commission (Commission) staff will hold a technical conference on February 26, 2014, from 9:00 a.m. to approximately 1:00 p.m. (Eastern Time), to discuss with interested parties whether to model Load Zone K as an export-constrained zone for future Demand Curve reset proceedings.[1]

The conference will be held at the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The technical conference will be led by staff, and will be open for the public to attend. The conference will include a background presentation by New York Independent System Operator, Inc. as well as technical questions from Commission Staff. There will also be opportunities for comments and questions from other conference attendees. The specific agenda and procedures to be followed at the conference will be announced by staff at the opening of the conference. Attendees should be prepared to discuss the following:

1. Whether Zone K (Long Island) can be modeled as export constrained Load Zone.

2. Whether Zone K should be included as a nested zone within the current G–J Locality so that the larger zone would become a G–K Locality. If not, what rationale supports allowing Zone K to be a nested zone within NYCA, but not a nested zone within the G–J Locality? Specifically, how can generation capacity located in Zone K be made available to serve the reliability needs of Zones A–F but not the reliability needs of Zones G–J?

3. Whether sufficient transmission capability exists to allow at least some capacity located in Zone K to reliably serve the needs of loads in Zones G–J. If so, what limits, if any, should be placed on the amount of capacity in Zone K that could be relied upon to serve the needs of loads in Zones G–J? How should those limits be determined?

The January 28, 2014 Notice of Technical Conference stated that there will be a free webcast of the conference available. We will not be able to provide webcasting for this event. However, those wishing to receive teleconferencing should inform us by Monday, February 24, by sending an email request to *sarah.mckinley@ferc.gov*. Please put ''teleconference request'' on the subject line, and include your name, email and telephone number. Teleconference information will be emailed to you by February 25, 2014. The technical conference will be transcribed.

Attendees may register in advance at the following Web page: *https://www.ferc.gov/whats-new/registration/zone-k-02–26–14-form.asp.* Advance registration is not required, but is encouraged. Parties attending in person should still allow time to pass through building security procedures before the 9:00 am (Eastern Time) start time of the conference.

Following the conference, the Commission will consider post-technical conference comments submitted on or before March 26, 2014. Answers to post-technical conference comments are due by close of business on or before April 16, 2014.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–502–8659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

All interested persons are permitted to attend. For more information about the technical conference, please contact:

Adria M. Woods (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8431, *Adria.Woods@ferc.gov.*

Sarah McKinley (Logistical Information), Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8004, *Sarah.McKinley@ferc.gov.*

Dated: February 19, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–04042 Filed 2–25–14; 8:45 am]

BILLING CODE 6717–01–P

[1] *New York Indep. Sys. Operator, Inc., 144 FERC ¶61,126 (2013).*

ENVIRONMENTAL PROTECTION AGENCY

[Petition IV–2011–1; FRL–9907–12-Region 9]

Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permit for Hu Honua Bioenergy Facility, LLC; Pepeekeo, Hawaii

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition to object to a state operating permit.

SUMMARY: Pursuant to Clean Air Act (CAA) Section 505(b)(2) and 40 CFR 70.8(d), the EPA Administrator signed an Order, dated February 7, 2014, partially granting and partially denying a petition to object to a CAA title V operating permit proposed by the Clean Air Branch, Environmental Management Division, Hawaii Department of Health (HDOH) for the Hu Honua Bioenergy Facility, LLC (Hu Honua) in Pepeekeo, Hawaii. For the Issues that EPA denied, the Order constitutes a final action on the petition submitted by the Law Office of Marc Chytilo, on behalf of Preserve Pepeekeo Health & Environment (Petitioner), on August 26, 2011. Pursuant to section 505(b)(2) of the CAA, a petitioner may seek judicial review in the United States Court of Appeals for the appropriate circuit of those portions of the petition which EPA denied. Any petition for review shall be filed within 60 days from the date this notice appears in the Federal

Register, pursuant to section 307 of the CAA.

ADDRESSES: Copies of the Order, the petition, and all pertinent information relating thereto are on file at the following location: EPA Region 9; Air Division; 75 Hawthorne Street; San Francisco, California 94105.

FOR FURTHER INFORMATION CONTACT: Gerardo Rios, Air Permits Office, EPA Region 9, at (415) 972–3974 or *rios.gerardo@epa.gov.*

SUPPLEMENTARY INFORMATION: The CAA affords EPA a 45-day period to review and, as appropriate, the authority to object to operating permits proposed by state permitting authorities under title V of the CAA, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the CAA and 40 CFR 70.8(d) authorize any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of EPA's 45-day review period if EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

The petitioner submitted a petition regarding Hu Honua on August 26, 2011, requesting that EPA object to the CAA title V operating permit, identified as Covered Source Permit Number 0724–01–C. The Petitioner alleged that the permit was not consistent with the CAA because: (1) EPA raised objectionable issues in its comment letter on the proposed permit; (2) the permit fails to ensure compliance with criteria air pollutant emission limits; (3) the permit fails to ensure compliance with Best Available Control Technology (BACT) requirements for CO; (4) the permit fails to ensure compliance with hazardous air pollutant (HAP) emission limits; (5) the baghouse is not adequately described or monitored; (6) the permit fails to ensure compliance with applicable state law and State Implementation Plan (SIP) requirements; (7) the permit fails to ensure compliance with Maximum Achievable Control Technology (MACT) requirements for major sources of HAPs; (8) the permit impermissibly exempts startups and shutdowns from emissions limits; (9) the facility's biomass handling, chipping, and storage operations do not qualify as an ''insignificant activity''; (10) the permit fails to address emissions from trona or lime and ash handling; (11) HDOH failed to address ammonia slip and sulfuric acid mist emissions; (12) HDOH failed to directly regulate and evaluate the impacts of $PM_{2.5}$; and (13) HDOH failed to adequately respond to significant public comments.

On February 7, 2014, the Administrator issued an Order partially granting and partially denying the petition. The Order explains EPA's rationale for partially granting and partially denying the petition.

Dated: February 11, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2014–04174 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2013–0611; FRL–9905–34]

Pesticide Maintenance Fee; Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellation, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1 of Unit II., pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a June 26, 2013, **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 of Unit II., to voluntarily cancel these product registrations. In the June 26, 2013 notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 180-day comment period that would merit further review of these requests, or unless the registrants withdrew their requests. The Agency received three requests from registrants withdrawing their requests for EPA Reg. Nos. 432–1473, 1677–90 and WA030027. Also, EPA Reg. No. OR030037 was cancelled under another **Federal Register** notice published on September 13, 2013. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including existing stocks provisions.

DATES: The cancellations are effective January 15, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Yanchulis, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0237; email address: *yanchulis.michael@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2013–0611. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces the cancellation, as requested by registrants, of 261 products registered under FIFRA section 3 and FIFRA section 24(c) which are listed in sequence by registration number in Table 1 of this unit.

TABLE 1—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT MAINTENANCE FEES

Registration No.	EPA Company No.	Product name	Chemical name
000100–00701	100	Amber Herbicide	Triasulfuron.
000100–00800	100	Ridomil Gold Bravo	D-Alanine, *N*-(2,6-dimethylphenyl-*N*-(methoxyacetyl)-,methyl ester; Chlorothalonil.
000100–00848	100	Zorial Rapid 80 Herbicide	Norflurazon.
000228–00557	228	Atera GC 2+1 SC Insecticide	Bifenthrin; Imidacloprid.
000239–02683	239	Ortho Home Pest Insect Killer	Bifenthrin.
000264–00378	264	Larvin Brand DF Thiodicarb Insecticide/Ovicide	Thiodicarb.
000264–00379	264	Larvin Brand 3.2 Thiodicarb Insecticide/Ovicide	Thiodicarb.
000264–00467	264	Aliette Fungicide	Fosetyl-Al.
000264–00504	264	Aliette Injectable Fungicide	Fosetyl-Al.
000264–00530	264	Larvin Brand DF WSP Thiodicarb Insecticide/Ovicide.	Thiodicarb.
000264–00700	264	Dropp SC Cotton Defoliant	Thidiazuron.
000264–00705	264	Scala 400 SC Fungicide	Pyrimethanil.
000264–00735	264	Sencor 4 Flowable Herbicide	Metribuzin.
000264–00737	264	Bayleton 50% Dry Flowable Fungicide	Triadimefon.
000264–00750	264	Raxil 0.26 FS Seed Treatment Fungicide	Tebuconazole.
000264–00782	264	Encore 190 Insecticide	Imidacloprid.
000264–00928	264	Gustafson Captan 30–DD	Captan.
000264–00931	264	Gustafson Captan 400	Captan.
000264–00939	264	Gustafson RTU-Baytan-Thiram Fungicide	Triadimenol.
000264–00949	264	Vitavax PC Peanut Seed Treatment Fungicide	Thiram; Carboxin; Pentachloronitrobenzene; Captan.
000264–00961	264	Raxil 0.26 FS Seed Treatment Fungicide	Tebuconazole.
000264–00965	264	Busan 30A	2-(Thiocyanomethylthio) benzothiazole.
000264–00966	264	Raxil XT Wettable Powder Fungicide	Tebuconazole; Metalaxyl.
000264–00973	264	Evolve Potato Seed Piece Treatment Fungicide	Cymoxanil; Thiophanate-methyl; Mancozeb.
000264–00975	264	Protege 70WP Fungicide	Azoxystrobin.
000264–00979	264	Protege-Allegiance WP Fungicide	Azoxystrobin; Metalaxyl.
000264–00982	264	Protege-FL Seed Applied Fungicide	Azoxystrobin.
000264–00990	264	Tops 30 Flowable Fungicide	Thiophanate-methyl.
000264–00991	264	Soygard L with Protege	Azoxystrobin; Metalaxyl.
000264–00999	264	Three Way Peanut Seed Treatment Fungicide	Metalaxyl; Trufloxystrobin; Captan.
000352–00636	352	DuPont Advion Cockroach Bait Station	Indoxacarb.
000352–00637	352	DuPont Provaunt 1.25 SC Insecticide	Indoxacarb.
000352–00646	352	DuPont Advion Ant Bait Station	Indoxacarb.
000352–00770	352	DuPont Aperion ST Insecticide	Indoxacarb.
000400–00469	400	Dimilin 25W Mushrooms	Diflubenzuron.
000400–00559	400	Protector-L	Thiram.
000432–01310	432	Merit 0.62 Granular	Imidacloprid.
000432–01311	432	Merit 2.5 G Greenhouse and Nursery Insecticide	Imidacloprid.
000464–00661	464	Bioban 2000	2-Methyl-3(2*H*)-isothiazolone; 5-Chloro-2-methyl-3(2*H*)-isothiazolone.
000464–00679	464	Tris Nitro Solid	2-(Hydroxymethyl)-2-nitro-1,3-propanediol.
000499–00430	499	Whitmire TC 148A Microencapsulated Concentrate—Contains Nylar.	Pyriproxyfen.
000499–00439	499	Whitmire TC 148B	Pyriproxyfen.
000499–00537	499	TC–296	Dinotefuran.
000499–00554	499	TC–329	Dinotefuran.
000524–00538	524	MON 78271 Herbicide	Glycine, *N*-phosphonomethyl) -potassium salt.
001448–00017	1448	Busan 11–M1	Barium metaborate.
001448–00023	1448	Busan 90	Ethanone, 2-bromo-1-(4-hydroxyphenyl)-.
001448–00045	1448	Busan 93	2-(Thiocyanomethylthio) benzothiazole; Ethanone, 2-bromo-1-(4-hydroxyphenyl)-.
001448–00075	1448	DCDIC	Carbamodithioic acid, cyano-, disodium salt.
001448–00342	1448	Busan 1130	Ethanone, 2-bromo-1-(4-hydroxyphenyl)-.
001448–00367	1448	Busan 90C	Ethanone, 2-bromo-1-(4-hydroxyphenyl)-.
001448–00386	1448	TCMTB 5WB	2-(Thiocyanomethylthio) benzothiazole.
001529–00033	1529	Nuosept 145 Preservative	Methanol, (((1-methyl-2-(5-methyl-3-oxazolidinyl) ethoxy)methoxy)methoxy)-.
001677–00056	1677	Bar Star Bar Glass Sanitizer	Dodecylbenzenesulfonic acid; Phosphoric acid.
001706–00237	1706	SD Algaecide	1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride.
002217–00692	2217	Gordon's Professional Turf Products Teremec SP Turf Fungicide.	Chloroneb.
002724–00592	2724	SPI Residual Pressurized Spray II	Pyrethrins; Permethrin; MGK 264.
002724–00642	2724	Speer Flea & Tick Spray IV	Pyrethrins; Permethrin; Piperonyl butoxide.
002724–00648	2724	Speer Neoperm Total Release Indoor Fogger IV	Tetramethrin; Permethrin; Piperonyl butoxide.
002724–00709	2724	Elite Quick-Kill Spray Concentrate	Pyrethrins; Piperonyl butoxide.
002724–00776	2724	Linalool Mousse	Pyriproxyfen; Prallethrin; MGK 264; Linalool.
005813–00049	5813	Clorox Toilet Bowl Cleanser	Sodium hypochlorite.
005887–00169	5887	Black Leaf Vitamin B1 Solution	1-Naphthaleneacetic acid.

TABLE 1—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT MAINTENANCE FEES—Continued

Registration No.	EPA Company No.	Product name	Chemical name
007173–00239	7173	Difethialone Block	Difethialone.
007173–00240	7173	Generation Blue Pellets Bait Packs	Difethialone.
007969–00249	7969	Bas 510 ST Seed Treatment Fungicide	Boscalid.
008622–00043	8622	Metapicrin	Chloropicrin.
009198–00094	9198	The Andersons Tee Time with 0.92% Team	Trifluralin; Benfluralin.
009198–00110	9198	The Andersons Tee Time Insecticide with 6.2% Dylox.	Trichlorfon.
009198–00112	9198	The Andersons 0.5% Bayleton Fungicide	Triadimefon.
009198–00153	9198	Andersons Fertilizer Weed & Feed with 0.92% Atrazine.	Atrazine.
009198–00155	9198	The Andersons Fertilizer with .1875% Dimension & 1.0% Ronstar.	Dithiopyr; Oxadiazon.
009198–00156	9198	The Andersons GC Fertilizer Plus 0.058% Bifenthrin	Bifenthrin.
009198–00161	9198	The Andersons 0.058% Bifenthrin Insect Control Plus Fertilizer.	Bifenthrin.
009198–00162	9198	The Andersons 0.029% Bifenthrin Insect Control Plus Fertilizer.	Bifenthrin.
009198–00171	9198	Anderson's Fertilizer Plus Pre-emergent Weed Control.	Pendimethalin.
009198–00174	9198	Anderson's Proturf Fertilizer Plus Weedgrass Control.	Pendimethalin.
009198–00186	9198	St. Augustine Weed Control Plus Fertilizer	Atrazine.
009198–00208	9198	Fertilizer Plus Fungicide XI	Myclobutanil.
009198–00218	9198	The Andersons 0.51% Granule Propiconazole	Propiconazole.
009198–00220	9198	Andersons Golf Products 30% Etradiazole Turf Fungicide.	Etridiazole.
009198–00221	9198	Andersons Golf Products Truban Fungicide 30% WP.	Etridiazole.
009198–00223	9198	The Andersons Insect Killer Granules with 2.0% Carbaryl.	Carbaryl.
009198–00238	9198	The Andersons 0.058% Bifenthrin + 0.115% Imidacloprid Insecticide with Fertilizer.	Bifenthrin; Imidacloprid.
009198–00240	9198	The Andersons GC 0.077% Bifenthrin + 0.155% Imidacloprid Granular Insecticide.	Bifenthrin; Imidacloprid.
009198–00241	9198	The Andersons GC 0.058% Bifenthrin + 0.115% Imidacloprid Insecticide with Fertilizer.	Bifenthrin; Imidacloprid.
009198–00246	9198	The Andersons 0.39% Trinexapac-Ethyl + Fertilizer	Trinexapac-ethyl.
009198–00248	9198	The Andersons 0.75% Prodiamine Herbicide	Prodiamine.
009198–00249	9198	The Andersons 0.5% Prodiamine Herbicide	Prodiamine.
010088–00083	10088	Prometon 12.5% Herbicide Concentrate	Prometon.
010163–00323	10163	Scythe L Herbicide	Nonanoic acid.
034704–00318	34704	Dormant Flowable Emulsion	Mineral oil.
034704–00337	34704	Niagara Citrus Sol Oil Light Medium Code 30390	Mineral oil.
054625–00002	54625	Brita Water Filter Travel Pak	Silver; Glycine, hydriodide (4:1), compound with iodine (4:5).
055146–00056	55146	Gibgro 5% Powder	Gibberellic acid.
055146–00086	55146	Agtrol 6–BA	Gibberellin; Benzyladenine.
060061–00005	60061	2000 Soft Sloughing Type Antifouling Paint	Cuprous oxide.
060061–00033	60061	Vinelast Antifouling Finish 720 Permanent Red	Cuprous oxide.
060061–00034	60061	Woolsey Vinelast Antifouling Racing Finish 733 Permanent Green.	Cuprous oxide.
060061–00035	60061	Woolsey Vinelast Antifouling Racing Finish 734 Permanent Blue.	Cuprous oxide.
060061–00051	60061	Pettit Marine Paint Antifouling 1210 Blue Tropic	Cuprous oxide.
060061–00065	60061	Pettit Marine Paint Unepoxy Tin Free Antifouling 1619 Red for Tropic.	Cuprous oxide.
060061–00077	60061	Neptune II Water Based Antifouling Finish 550 Blue	Cuprous oxide.
066330–00271	66330	Dimethoate Technical	Dimethoate.
067071–00002	67071	Acticide PM	Chlorothalonil; Diuron.
067071–00036	67071	Microcare ITA	2-Methyl-3(2*H*)-isothiazolone; 5-Chloro-2-methyl-3(2*H*)-isothiazolone.
067071–00045	67071	Acticide MBL 5515	1,2-Benzisothiazlin-3-one; Bronopol.
067071–00059	67071	Acticide CBM–F	5-Chloro-2-methyl-3(2*H*)-isothiazolone; 1,2-Benzisothiazolin-3-one; 2-Methyl-3(2*H*)-isothiazolone.
067619–00018	67619	Silvio	Silver; Citric acid.
070404–00009	70404	Tinosan SDC–R	Silver; Citric acid.
074655–00002	74655	Spectrum RX–33	Sodium chlorite.
074655–00004	74655	Spectrum RX–32	Methylene bis (thiocyanate).
074655–00009	74655	Spectrum RX–508	2,2-Dibromo-3-nitrilopropionamide.

TABLE 1—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT MAINTENANCE FEES—Continued

Registration No.	EPA Company No.	Product name	Chemical name
074655–00010	74655	Spectrum RX–65	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}); Bis(trichloromethyl) sulfone.
074655–00022	74655	Amerstat 300	2,2-Dibromo-3-nitrilopropionamide.
074655–00029	74655	Drewborm Precursor	Sodium bromide.
075318–00006	75318	B2E–01	*S*-Methoprene.
083222–00024	83222	Bifen 2 Ag Gold-Cal	Bifenthrin.
AL110001	100	Gramoxone Inteon	Paraquat dichloride.
AR070007	264	Ricestar HT Herbicide	Fenoxaprop-p-ethyl.
AR090001	81880	Permit Herbicide	Halosulfuron.
AR110001	10163	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
AR120010	81880	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
AR120011	81880	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
AR120012	81880	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
AR120013	81880	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
AR120015	81880	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
AR810044	264	Monitor 4	Methamidophos.
AR870007	264	Monitor 4	Methamidophos.
AR940001	59639	Valent Bolero 10 G	Thiobencarb.
AZ030004	66222	Thiodan 3 EC Insecticide	Endosulfan.
AZ080005	352	DuPont Layby Pro Herbicide	Diuron; Linuron.
AZ880001	264	Rovral Fungicide	Iprodione.
AZ910004	10163	Gowan Trifluralin 10G	Trifluralin.
AZ980004	19713	Drexel Endosulfan 3EC	Endosulfan.
CA040015	66222	Galigan 2E Oxyfluorfen Herbicide	Oxyfluorfen.
CA040018	66222	Galigan 2E Oxyfluorfen Herbicide	Oxyfluorfen.
CA040019	100	Subdue Maxx	D-Alanine, *N*-(2,6-dimethylphenyl-*N*-(methoxyacetyl)-, methyl ester.
CA060014	62719	M-Pede	Potassium laurate.
CA070009	66222	Rimon 0.83 EC	Novaluron.
CA790188	264	Monitor 4	Methamidophos.
CA810059	264	Sevin Brand Sprayable Carbaryl Insecticide	Carbaryl.
CA960002	34704	Western Farm Service Dusting Sulfur	Sulfur.
CA960006	62719	Eagle WSP Fungicide	Myclobutanil.
CA970014	62719	Goal (R) 2XL Herbicide	Oxyfluorfen.
CA980001	264	Provado 1.6 Flowable	Imidacloprid.
CA990015	62719	Confirm 2F Agricultural Insecticide	Tebufenozide.
CO080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
DE010002	264	Sevin XLR Plus Carbaryl Insecticide	Carbaryl.
DE040002	55146	Phostrol Agricultural Fungicide	Phosphorous acid.
DE060001	66222	Diazinon AG500	Diazinon.
FL000007	62719	Dithane DFAgricultural Fungicide	Mancozeb.
FL000012	59639	Select Herbicide	Clethodim.
FL040008	50534	Bravo Ultrex	Chlorothalonil.
FL090011	279	Fury 1.5 EW Insecticide	Zeta-Cypermethrin.
FL890036	264	Sevin Brand 80 S Carbaryl Insecticide	Carbaryl.
FL890037	264	Sevin Brand 4F Carbaryl Insecticide	Carbaryl.
GA040004	50534	Bravo Ultrex	Chlorothalonil.
GA100005	100	Gramoxone Inteon	Paraquat dichloride.
GA110004	66222	Cotoran 4L	Fluometuron.
HI030001	66222	Thionex 50W	Endosulfan.
HI070006	66222	Thionex 3EC	Endosulfan.
HI090004	2935	HBT—Imaz	Imazapyr, isopropylamine salt.
HI910008	34704	Superior 70 Oil	Mineral oil.
IA080002	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
ID000016	352	Curzate 60DF	Cymoxanil.
ID030002	66222	Thionex 3EC	Endosulfan.
ID030016	10163	Carzol SP Miticide/insecticide In water soluble packaging.	Formetanate hydrochloride.
ID060018	66222	Abba 0.15EC	Abamectin.
ID080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
ID080016	100	Dual II Magnum	*S*-Metolachlor.
IL080002	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
IN980002	100	Princep Caliber 90 Herbicide	Simazine.
KS020001	7969	Distinct Herbicide	Diflufenzopyr-sodium; Dicamba, sodium salt.
KS040006	66222	Atrazine 4L	Atrazine.
KS040008	62719	NAF–127	Spinosad.
KS110003	7173	Rozol Prairie Dog Bait	Chlorophacinone.
KS120002	7173	Rozol Prairie Dog Bait	Chlorophacinone.
LA010010	241	Scepter 70 DG Herbicide	Imazaquin.

TABLE 1—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT MAINTENANCE FEES—Continued

Registration No.	EPA Company No.	Product name	Chemical name
LA020006	62719	Confirm 2F Agricultural Insecticide	Tebufenozide.
LA060009	7969	Termidor 80 WG Termiticide/insecticide	Fipronil.
LA060010	7969	Termidor SC Termiticide/insecticide	Fipronil.
LA090003	100	Reflex Herbicide	Sodium salt of fomesafen.
LA090004	279	Mustang Max EW Insecticide	Zeta-Cypermethrin.
LA100001	10163	Onager Miticide	Hexythiazox.
LA110002	10163	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
ME000003	62719	Mimic 2LV	Tebufenozide.
ME080003	352	Dupont Express Herbicide with total soluble granules.	Tribenuron-methyl.
MN020010	100	Trinexapac Liquid	Trinexapac-ethyl.
MN080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
MN080008	352	DuPont Coragen Insect Control	Chlorantraniliprole.
MO090001	100	Reflex Herbicide	Sodium salt of fomesafen.
MO110002	100	Callisto Herbicide	Mesotrione.
MO120005	100	Callisto Herbicide	Mesotrione.
MS020022	352	Super Boll	Ethephon.
MS060011	66222	Abba 0.15EC	Abamectin.
MS060013	352	DuPont Classic Herbicide	Chlorimuron.
MS090004	100	Reflex Herbicide	Sodium salt of fomesafen.
MS110002	81880	Permit Plus	Thifensulfuron; Halosulfuron-methyl.
MT080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
NC060004	100	Gramoxone Inteon	Paraquat dichloride.
NC080001	66222	Thionex 3EC	Endosulfan.
NC080004	352	DuPont Linex 4L Herbicide	Linuron.
NC090006	66330	Permethrin 3.2 AG	Permethrin.
NC110002	100	Gramoxone Inteon	Paraquat dichloride.
ND020001	62719	Treflan H.F.P.	Trifluralin.
ND080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
ND080002	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
NE020003	7969	Distinct Herbicide	Diflufenzopyr-sodium; Dicamba, sodium salt.
NE080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
NE080002	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
NJ030004	100	Dual Magnum Herbicide	*S*-Metolachlor.
NJ040001	100	Dual Magnum Herbicide	*S*-Metolachlor.
NJ060001	100	Gramoxone Inteon	Paraquat dichloride.
NJ990004	100	Dual Magnum Herbicide	*S*-Metolachlor.
NJ990005	100	Dual Magnum Herbicide	*S*-Metolachlor.
NM010001	264	Balance Flexx Herbicide	Isoxaflutole.
NM080003	7969	Endura Fungicide	Boscalid.
NV060010	66222	Abba 0.15EC	Abamectin.
NY010002	62719	Confirm 2F Agricultural Insecticide	Tebufenozide.
NY020001	100	Actara	Thiamethoxam.
NY100002	100	Platinum Insecticide	Thiamethoxam.
NY100003	100	Flagship 25WG	Thiamethoxam.
NY100004	100	Flagship 0.22G	Thiamethoxam.
NY100005	100	Endigo ZC	Lambda-Cyhalothrin; Thiamethoxam.
NY100006	100	Platinum 75 SG Insecticide	Thiamethoxam.
NY110002	7969	Bas 556 SC	Metconazole; Pyraclostrobin.
OH050001	66222	Rimon 0.83 EC	Novaluron.
OH080001	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
OR000007	100	Trinexapac Liquid	Trinexapac-ethyl.
OR030008	66222	Equus DF	Chlorothalonil.
OR030012	66222	Thionex 50W Insecticide	Endosulfan.
OR030013	66222	Thiodan 3 EC Insecticide	Endosulfan.
OR030024	66222	Thiodan 3 EC Insecticide	Endosulfan.
OR060020	62719	Laredo EC	Myclobutanil.
OR990037	100	Bravo 825	Chlorothalonil.
OR990038	100	Bravo 720	Chlorothalonil.
SC100001	100	Endigo ZC	Lambda-Cyhalothrin; Thiamethoxam.
SC100004	100	Gramoxone Inteon	Paraquat dichloride.
SC110002	100	Reflex Herbicide	Sodium salt of fomesafen.
SC900004	100	Reflex 2lC Herbicide	Sodium salt of fomesafen.
SD040002	7969	Pristine Fungicide	Pyraclostrobin; Boscalid.
SD040003	7969	Emerald Fungicide	Boscalid.
SD060005	7969	Outlook Herbicide	Dimethenamide-P.
SD920007	279	Capture 2 EC	Bifenthrin.
TN090002	100	Reflex Herbicide	Sodium salt of fomesafen.
TX100001	10163	Onager Miticide	Hexythiazox.
TX100012	279	Fury 1.5 EW Insecticide	Zeta-Cypermethrin.

TABLE 1—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT MAINTENANCE FEES—Continued

Registration No.	EPA Company No.	Product name	Chemical name
UT070003	400	Acramite-4SC	Befenazate.
UT070004	66222	Rimon 0.83 EC	Novaluron.
VA010001	59639	Distance Insect Growth Regulator	Pyriproxyfen.
VA089999	59639	Safari 20 SG Insecticide	Denotefuran.
WA010034	66222	Galigan 2E	Oxyfluorfen.
WA010037	66222	Galigan 2E	Oxyfluorfen.
WA090012	62719	Lorsban Advanced	Chlorpyrifos.
WA100001	264	Sevin Brand 4F Carbaryl Insecticide	Carbaryl.
WA990001	264	Ethrel Brand Ethephon Plant Regulator	Ethephon.
WI010008	66330	Iprodione 4l AG	Iprodione.
WY080002	279	Mustang Max EC Insecticide	Zeta-Cypermethrin.
WY120003	7173	Rozol Prairie Dog Bait	Chlorophacinone.

Table 2 of the unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
100	Syngenta Crop Protection, LLC., P.O. Box, 18300, Greensboro, NC 27419–8300.
228	Nufarm Americas, Inc., 4020 Aerial Center Pkwy., Suite 103, Morrisville, NC 27560.
239	The Scotts Company, D/B/A The Ortho Group, P.O. Box 190, Marysville, OH 43030.
241	BASF Corp., P.O. Box 13528, Research Triangle Park, NC 27709–3528.
264	Bayer CropScience LP., P.O. Box 12014, Research Triangle Park, NC 27709.
279	FMC Corp., Agricultural Products Group, 1735 Market St., Rm. 1978, Philadelphia, PA 19103.
352	E.I. Du Pont de Nemours & Co., 1007 Market Street, Wilmington, DE 19898–0001.
400	Chemtura Corp., 199 Benson Rd., Middlebury, CT 06749.
432	Bayer Environmental Science, A Division of Bayer CropScience LP., P.O. Box 12014, Research Triangle Park, NC 27709.
464	The Dow Chemical Company, 1500 East Lake Cook Road, Buffalo Grove, IL 60089.
499	Whitmire Micro-Gen Research Laboratories, Inc., 3568 Tree Court Industrial Blvd., St. Louis, MO 63122–6682.
524	Monsanto Company, 1300 I Street NW., Suite 450 E., Washington, DC 20005.
1448	Buckman Laboratories Inc., 1256 North McLean Blvd., Memphis, TN 38108.
1529	International Specialty Products, An Ashland Inc. Business, 1361 Alps Road, Wayne, NJ 07470.
1677	Ecolab Inc., 370 North Wabasha Street, St. Paul, MN 55102.
1706	Nalco Company, A Subsidiary of Ecolab Inc., 370 North Wabasha Street, St. Paul, MN 55102.
2217	PBI/Gordon Corp., P.O. Box 014090, Kansas City, MO 64101–0090.
2724	Wellmark International, 1501 E. Woodfield Rd., Suite 200 W., Schaumburg, IL 60173.
2935	Wilbur-Ellis Company, P.O. Box 1286, Fresno, CA 93715
5813	The Clorox Co., C/O PS&RC, P.O. Box 493, Pleasanton, CA 94566–0803.
5887	Value Gardens Supply, LLC., 9100 W. Bloomington Freeway, Suite 113, Bloomington, MN 55431.
7173	Liphatech, Inc., 3600 W. Elm Street, Milwaukee, WI 53209.
7969	BASF Corp., Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709–3528.
8622	ICL–IP America, Inc., 95 Maccorkle Ave., Southwest, South Charleston, WV 25303.
9198	The Andersons Lawn Fertilizer Division, Inc., P.O. Box 119, Maumee, OH 43537.
10088	Athea Laboratories Inc., P.O. Box 240014, Milwaukee, WI 53224.
10163	Gowan Co., P.O. Box 5569, Yuma, AZ 85366–8844.
19713	Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–0327.
34704	Loveland Products, Inc., P.O. Box 1286, Greeley, CO 80632–1286.
50534	GB Biosciences Corp., P.O. Box 18300, Greensboro, NC 27419–5458.
54625	The Brita Products Co., C/O PS&RC, P.O. Box 493, Pleasanton, CA 94566–0803.
55146	Nufarm Americas, Inc., 4020 Aerial Center Pkwy., Suite 103, Morrisville, NC 27560.
59639	Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596.
60061	Kop-Coat, Inc., 3020 William Pitt Way, Pittsburgh, PA 15238.
62719	Dow Agrosciences LLC., 9330 Zionsville Road, Indianapolis, IN 46268–1054.
66222	Makhteshim Agan of North America, Inc., 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.
66330	Arysta Lifescience North America, LLC., 15401 Weston Parkway, Suite 150, Cary, NC 27513.
67071	Thor GMBH, c/o Thor Specialties Inc., 50 Waterview Drive, Shelton, CT 06484.
67619	Clorox Professional Products Company, C/O PS&RC, P.O. Box 493, Pleasanton, CA 94566–0803.
70404	BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932.
74655	Hercules Incorporated, A Wholly Owned Subsidiary of Ashland Inc., 7910 Baymeadows Way, Suite 100, Jacksonville, FL 32256.
75318	B2E Biotech LLC., 1501 East Woodfield Road, Schaumburg, IL 60173.
81880	Canyon Group LLC., C/O Gowan Company, 370 S. Main Street, Yuma, AZ 85364.
83222	Direct Ag Source, LLC., P.O. Box 538, Eldora, IA 50627.

III. Summary of Public Comments Received or Withdraw of Requests and Agency Response

During the public comment period provided, EPA received three requests from registrants, withdrawing their requests for cancellation in response to the June 26, 2013, **Federal Register** notice (78 FR 38319) (FRL–9388–4) announcing the Agency's receipt of requests for voluntary cancellation of products listed in Table 1 of Unit II. through the Maintenance Fee process. The Agency is thus retaining the registration for EPA Reg. Nos. 432–1473, 1677–90 and WA030027.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations of the registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 or Unit II., are canceled. The effective date of the cancellations that are subject to this notice is January 15, 2014. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II., in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI., will be a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of June 26, 2013. The comment period closed on December 23, 2013.

VI. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be January 15, 2014. EPA will prohibit the continued sale and distribution of existing stocks of these products after the effective date of this cancellation.

List of Subjects

Environmental protection, Administrative practice and procedure, Pesticides and pests.

Dated: January 29, 2014.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2014–04097 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2009–0112; FRL–9906–46]

Toxic Substances Control Act Chemical Testing; Receipt of Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing its receipt of test data submitted pursuant to a test rule issued by EPA under section 4 of the Toxic Substances Control Act (TSCA). This document identifies a chemical substance for which test data have been received; lists uses or intended uses of such chemical substance; and describes the nature of the test data received. This is also part of EPA's commitment to strengthen its chemicals management programs by improving access to and the usefulness of chemical information. The goal is for people to easily get information to make safe chemical choices.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kathy Calvo, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8089; fax number: (202) 564–4765; email address: *calvo.kathy@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are concerned about data on public health and/or environmental effects and other characteristics of this chemical. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0112, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. Test Data Submissions

Section 4(d) of TSCA (15 U.S.C. 2603(d)) requires EPA to publish a notice in the **Federal Register** reporting the receipt of test data submitted pursuant to test rules promulgated under section 4(a) (15 U.S.C. 2603(a)). Each notice must:

1. Identify the chemical substance or mixture for which data have been received.
2. List the uses or intended uses of such chemical substance or mixture and the information required by the applicable standards for the development of test data.
3. Describe the nature of the test data developed.

EPA has received test data for the following test rule:

EPA received data on the chemical substance benzene, 1-chloro-4-(trifluoromethyl)-, (CAS No. 98–56–6) listed in the TSCA section 4 test rule titled ''Testing for Certain High Production Volume Chemicals; Third Group of Chemicals,'' published in the **Federal Register** issue of October 21, 2011 (76 FR 65385) (FRL–8885–5) (docket ID number EPA–HQ–OPPT–2009–0112).

The table in this unit contains the described information required by TSCA section 4(d). See the applicable CFR citation, listed in the title of the table, for test data requirements. Data received can be found by referencing the docket ID number and document number listed in the table. See Unit I.B. for additional information about dockets. EPA reviews of test data are added to the appropriate docket upon completion.

DATA RECEIVED IN RESPONSE TO TSCA SECTION 4 TEST RULE AT 40 CFR 799.5089; DOCKET IDENTIFICATION NUMBER EPA–HQ–OPPT–2009–0112

Chemical identity	Uses	Data received	Document number
Benzene, 1-chloro-4-(trifluoromethyl)-(CAS No. 98–56–6).	Solvent for industrial cleaning, aerosols, adhesives, coatings, inks, and electronic applications; dye intermediate; dielectric fluid; dinitroaniline herbicide intermediate.	Toxicity to Green Algae.	0224

Note: CAS No. = Chemical Abstracts Service Registry Number.

Authority: 15 U.S.C. 2603.

List of Subjects

Environmental protection, Hazardous substances.

Dated: February 13, 2014.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2014–04166 Filed 2–25–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[PS Docket No. 10–255 and PS Docket No. 11–153; FCC 14–6]

Facilitating the Deployment of Text-to-911 and Other Next Generation 911 Applications; Framework for Next Generation 911 Deployment

AGENCY: Federal Communications Commission.

ACTION: Policy Statement.

SUMMARY: The Federal Communications Commission (Commission) adopts a Policy Statement expressing its belief that every CMRS carrier and every provider that enables a consumer to send text messages using numbers from the North American Numbering Plan should support text-to-911 capabilities. The Commission intends to pursue a technologically-neutral approach that provides platform-independent norms for all stakeholders, based on high-level functional standards set by the relevant stakeholders in industry and the public safety community.

FOR FURTHER INFORMATION CONTACT: Timothy May, Public Safety and Homeland Security Bureau, (202) 418–1463 or *timothy.may@fcc.gov.*

SUPPLEMENTARY INFORMATION: People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Policy Statement

The Federal Communications Commission (Commission) believes that every CMRS carrier and every provider that enables a consumer to send text messages using numbers from the North American Numbering Plan should support text-to-911 capabilities.

The Commission intends to pursue a technologically-neutral approach that provides platform-independent norms for all stakeholders, based on high-level functional standards set by the relevant stakeholders in industry and the public safety community. Stakeholders should develop implementation details on a consensual basis in a manner that enables fact-based monitoring of progress by the relevant industry bodies, 911 and public safety authorities, and regulatory agencies. If the multi-stakeholder process achieves these values in a timely manner, we envision that any overarching functional rule adopted by the Commission would not need to impose additional obligations beyond those agreed to in the multi-stakeholder context. Rather, we expect that it would be needed only to codify the multi-stakeholder standard so it applies to all providers equally (including future entrants into the market) in a manner that brings regulatory clarity so that all participants in the 911 ecosystem can plan accordingly.

The Commission is particularly pleased that certain carriers have taken a leadership role on this issue and worked with public safety organizations to establish a May 15, 2014, deadline by which those carriers would support text-to-911 service nationwide. We encourage CMRS and interconnected text providers that are not parties to the Carrier-NENA–APCO Agreement to work with the public safety community to develop similar commitments to support text-to-911 in a timely manner, so that all consumers will be assured access to text-to-911 regardless of what text provider they choose.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2014–04230 Filed 2–25–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012084–004.

Title: HLAG/Maersk Line Gulf-South America Slot Charter Agreement.

Parties: A.P. Moller-Maersk A/S and Hapag-Lloyd AG.

Filing Party: Joshua P. Stein; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment deletes references to authority relating to the chartering of space between the parties in the Gulf-Central America trade, as such authority is now set forth in another slot charter agreement.

Agreement No.: 012248.

Title: MOL/NMCC/WLS Joint Operating Agreement.

Parties: Mitsui O.S.K. Lines, Ltd.; Nissan Motor Car Carrier Co., Ltd.; and World Logistics Service (U.S.A.), Inc.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 401 9th Street NW., Suite 900; Washington, DC 20004.

Synopsis: The agreement authorizes the parties to engage in operational and commercial cooperation in the U.S. trades.

By Order of the Federal Maritime Commission.

Dated: February 21, 2014.

Karen V. Gregory,

Secretary.

[FR Doc. 2014–04182 Filed 2–25–14; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 13, 2014.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Rick A. Tromble and Michele L. Tromble, individually and as trustees of the Rick A. Tromble Revocable Living Trust and the Michele L. Tromble Revocable Living Trust,* both of Cheboygan, Michigan; to retain voting shares of CNB Corporation, and thereby indirectly retain voting shares of Citizens National Bank of Cheboygan, both in Cheboygan, Michigan.

Board of Governors of the Federal Reserve System, February 21, 2014.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2014–04162 Filed 2–25–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The 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 March 24, 2014.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Otten Holdings, LLC,* Norfolk, Nebraska; to become a bank holding company by acquiring at least 33 percent of the voting shares of FEO Investments, Inc., and thereby indirectly acquire Elkhorn Valley Bank and Trust, both in Norfolk, Nebraska.

In connection with this application, Applicant also has applied to engage in general insurance activities in a town not exceeding 5,000 in population and community development activities, pursuant to sections 225.28(b)(11)(iii)(A) and (b)(12)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, February 21, 2014.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2014–04161 Filed 2–25–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14–14KW]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

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; 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. Written comments should be received within 60 days of this notice.

Proposed Project

Measuring the Effects of State and Local Radon Policies—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Lung cancer is the leading cause of cancer-related death in the U.S. population, with only 17% of lung cancer patients surviving 5 years or more from the time of diagnosis. Radon is a radioactive gas that concentrates in homes and is well-established as the leading cause of lung cancer in non-smokers and the second leading cause of lung cancer in smokers. Radon exposure reduction is the focus of two Healthy People 2020 objectives related to reduction of the number of people living in high-concentration radon homes and the subject of a ''Call to Action'' from

the US Surgeon General. Despite these recommendations, it is estimated that fewer than 25% of existing U.S. homes have been tested for radon.

There are significant gaps in understanding the impact of radon control efforts, especially those in the area of policy. As of February 2013, 22 states required general disclosure of known environmental hazards (including radon) during home sale, 21 states had radon professional licensure policies, and 8 states required notification of radon risks and test results as separate documents during a home sale. Twenty-one states had no radon-related policies. To date there are no studies that assess the effect of radon-related policies on increasing awareness or testing of radon and decreasing exposure to this well-known carcinogen.

To address this gap in knowledge, CDC proposes to conduct a new study to understand how state and local radon policies affect radon awareness, testing, and mitigation. The primary focus of the study will be on how single-family homebuyers and real estate agents understand and are affected by radon policies involving home sales. This information will allow stakeholders to better understand the impact of various policies intended to prevent exposure to radon and decrease the incidence of lung cancer in the U.S. population.

The study approach will involve complementary qualitative and quantitative methods whose results will guide future research and educational efforts. The main outcomes evaluated will be the effect of policies related to generic disclosure of environmental hazards at the time of home sale, notification specific to awareness of and test results for radon at the time of home sale, and radon professional certification. Participants' understanding of the Environmental Protection Agency (EPA) lead-based paint disclosure law, which is present in all states, will be assessed to understand if general environmental awareness differs between states.

Investigators seek to interview and send questionnaires to participants from four states: two states with home sale notification policies specific to radon, one state with only a generic disclosure law, and one state with no environmental disclosure policy. An additional consideration for recruiting these four states is to identify two states that have radon professional certification policies to compare to two states that do not.

After recruiting states with the desired mix of characteristics, investigators will focus on identifying counties or jurisdictions that have a median home sales price that approximates the median home price of the relevant Metropolitan Statistical Area. This will improve the ability to apply findings to other situations.

The Homebuyer Component of the study will involve information collection from 3,000 individuals (750 from each state) who purchased a single-family home in the last 12 months. Potential respondents for the Homebuyer Survey will be identified through review of publicly-available tax records of home sales and recruited through mailed invitations. The survey will ask questions regarding homebuyers' knowledge about radon and lead-based paint as well as how home sale and professional certification policies for radon and lead-based paint affected their decisions during the home buying process. Responses will be collected via mail and the internet. To improve the quality of information collected through the Homebuyer Survey, a draft instrument will be cognitively tested with up to 32 respondents before the final survey is distributed.

The Real Estate Agent Component of the study will involve focus groups with full-time real estate agents who specialize in single-family home sales and are members of a national, state, or an equivalent realtors association. Respondents will be recruited through mailed invitations to real estate offices, phone calls, and possibly outreach at local real estate agent meetings. Investigators will conduct three, one-hour focus groups of 6–8 agents per state for a total of up to 96 respondents. These recorded discussions will ask real estate agents about their and their clients' understanding of radon and lead, how/whether this understanding affected decisions during the home buying process, and whether professional certification affected decisions during the home buying process.

Understanding how these policies affect homebuyers and real estate agents will allow help stakeholders better prevent radon exposure and decrease the incidence of lung cancer in the U.S. population. This information will help provide an evidence basis for CDC's many grantees who work to understand the impact of policies in their states. OMB approval is requested for two years. Participation is voluntary and there are no costs to respondents other than their time.

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)
Homebuyers	Cognitive Testing Interview Guide	16	1	1	16
	Homebuyer Survey	1,500	1	8/60	200
Real Estate Agents	Focus Group Interview Guide	48	1	1	48
Total					264

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. 2014–04136 Filed 2–25–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–14KE]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

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; 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. Written comments should be received within 60 days of this notice.

Proposed Project

A Comprehensive Evaluation of a Paid Social Media and Mass Media Gynecologic Cancer Campaign—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2006, Congress passed The Gynecologic Cancer Education and Awareness Act (Pub. L. 111–324, ''Johanna's Law'') authorizing CDC to launch and evaluate a public health information campaign regarding gynecological cancers. The campaign, entitled ''Inside Knowledge: Get the Facts About Gynecologic Cancer,'' seeks to increase women's intentions to seek medical attention for persistent symptoms that could be indicative of some of gynecological cancers, yet may sometimes be ignored or simply overlooked by women. The campaign is managed by the Division of Cancer Prevention and Control (DCPC) at the Centers for Disease Control and Prevention (CDC).

CDC plans to evaluate the Inside Knowledge campaign by collecting information from members of its target audience: adult women (ages 40–65) in the United States. Information will be collected through self-administered, Web-based surveys. Survey items will include measures of audience recall of the campaign; perceptions of campaign messages; gynecologic health related knowledge, attitudes, and beliefs; intentions to seek care for symptoms associated gynecologic cancers; and sociodemographic characteristics. Specifically, this information collection will allow CDC to assess exposure to campaign efforts and assess whether women who were exposed to the campaign have higher awareness of the campaign, higher knowledge of gynecological cancers, and greater intentions to seek medical attention for gynecologic cancer symptoms and/or to discuss symptoms with their doctor. The evaluation will also examine whether women's awareness of the campaign differs by channel of delivery.

To conduct the evaluation, we will augment the national Inside Knowledge campaign with an additional paid media campaign in two cities. Cities will be selected based on the following criteria: (1) Incidence/prevalence of gynecologic cancer, (2) cost of mass media advertising, (3) size of the target audience in the city, (4) similarity in population size and demographics, and (5) previous Inside Knowledge campaign activities within the city. The two locations selected for this evaluation study will fall within the Nielsen 35–45 Designated Market Area (DMA) designations. The additional campaign advertising will include digital media and traditional media that will be implemented in flights, including the following: (1) A higher concentration in a defined time (''heavy up'') of traditional media only, (2) digital media only, and (3) a combination of a ''heavy up'' along with digital media. Each city will be non-randomly assigned to a condition, i.e., the type (traditional or digital) and sequence of additional advertisements. Evaluation information will be collected at four time points in each city (a baseline survey plus up to three additional surveys after each flight of additional media). To reduce attrition and eliminate time-in-sample bias that would artificially increase measures of campaign recognition, we will use address-based, cross-sectional sampling methods to randomly select respondents for each survey. The address-based sampling will also increase the likelihood that respondents live within the cities where the media campaigns are implemented. Potential respondents will receive an advance letter that describes the study and provides a link to the survey Web site. The total number of respondents in each study location is approximately 2,424.

Results of this evaluation study will be used to inform CDC, policymakers, prevention practitioners, researchers, and the general U.S. population about the reach and impact of the Inside Knowledge gynecologic health awareness campaign, and to inform the development and implementation of future health communication efforts.

OMB approval is requested for one year. The same survey instrument will be used for all information collection.

Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avgerage burden per response (in hr)	Total burden (in hr)
Women Ages 45–60 in City 1	Women's Health Survey	2,424	1	20/60	808
Women Ages 45–60 in City 2	Women's Health Survey	2,424	1	20/60	808

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avgerage burden per response (in hr)	Total burden (in hr)
Total					1,616

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. 2014–04135 Filed 2–25–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 11:00 p.m.–2:00 p.m., Eastern Time, March 19, 2014.

Place: Audio Conference Call via FTS Conferencing.

Status: Open to the public. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: This Advisory Board is charged with a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: The agenda for the conference call includes: Final Vote Tally for Joslyn Manufacturing Plant SEC Petition Action; Subcommittee and Work Group Updates; SEC Petition Evaluations Update for the April 2014 Advisory Board Meeting; Plans for the April 2014 Advisory Board Meeting; and Advisory Board Correspondence.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore M. Katz, M.P.A., Designated Federal Official, NIOSH, CDC, 1600 Clifton Road NE., Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1–800–CDC–INFO, Email *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–04085 Filed 2–25–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women (ACBCYW)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates:

9:00 a.m.–5:30 p.m. EST, March 27, 2014

8:00 a.m.–12:00 p.m. EST, March 28, 2014

Place: Centers for Disease Control and Prevention, 4770 Buford Highway, Chamblee Building 107 1A/1B/1C, Atlanta, Georgia 30341

Status: The meeting is open to the public, for in-person or distance participation, limited only by the space and phone lines available. For offsite participation, call (1) toll free: 888–989–8135 Participant passcode 4798; or (2) by Net Conference at URL *https://www.mymeetings.com/nc/join/* *Conference* number: PW4485905 Audience passcode: 4798; or (3) join the meeting directly at: *https://www.mymeetings.com/nc/join.php?i=PW4485905&p=4798&t=c.*

Participants outside of the U.S. may join by calling toll free 1–415–228–4965 Participant passcode: 4798.

Purpose: The committee provides advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly

among those at heightened risk) and promotes the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Matters for Discussion: The agenda will include discussions on the current and emerging topics related to breast cancer in young women. These may include applied research, public health communication, approaches to increase awareness around topics such as breast cancer risk, breast health, symptoms, diagnosis, and treatment of breast cancer in young women.

Agenda items are subject to change as priorities dictate. Online Pre-Registration Required: To expedite the security clearance process required for entry into a Federal building, all ACBCYW attendees must register for the meeting online at least seven days in advance at *http://www.cdc.gov/cancer/breast/what_cdc_is_doing/meetings.htm.*

Please complete all the required fields before submitting your registration and submit no later than March 19, 2014. Each meeting day, attendees must provide CDC staff and security with driver's license, state issued ID, or passport.

Contact Person for More Information: Temeika L. Fairley, Ph.D., Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 5770 Buford Highway, NE., Mailstop K52, Atlanta, Georgia 30341, Telephone (770) 488–4518, Fax (770) 488–4760.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–04084 Filed 2–25–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

Notice of Cancellation/Correction: CDC published a notice in the **Federal Register** on December 27, 2013, Volume 78, Number 249, Pages 78964–78965, to announce a February 6, 2014, Audio Conference Call of the ABRWH–SDRR. This meeting was canceled due to a lack of quorum for the meeting. Notice will be provided when the meeting is rescheduled, in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463). CDC published a cancellation notice in the **Federal Register** on February 14, 2014, Volume 79, Number 31, Pages 8970–8971, that incorrectly identified the ABRWH–SDRR committee as the ''Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID)''.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., Mailstop E–20, Atlanta Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email *ocas@cdc.gov.*

This notice is published less than the required 15 days prior to the start of the announced meeting, in accordance with Section 102–3.150(b) of the GSA Final Rule (2001) that allows for exceptions to the meeting notification time requirement. Section 102–3.150(b) states the following: ''In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 calendar days'' notice, provided that the reasons for doing so are included in the advisory committee meeting notice published in the **Federal Register**.''

In this case, the agency is giving less than 15 days' notice due to the inability to have quorum for the meeting.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–04086 Filed 2–25–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ACF Program Instruction: Children's Justice Act

OMB No.: 0970–0425

Description: The Program Instruction, prepared in response to the enactment of the Childrens Justice Act (CJA), Title II of Public Law 111–320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the States and Territories to accomplish the purposes of assisting States in developing, establishing and operating programs designed to improve: (1) The assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the child's family; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, including child sexual abuse and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111–320 at Sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.

Respondents: State Governments

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application & Annual Report	52	1	60	3,120

Estimated Total Annual Burden Hours: 3,120

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF 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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–04094 Filed 2–25–14; 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: Child Support Enforcement Program Expenditure Report (Form OCSE–396) and the Child Support Enforcement Program Collection Report (Form OCSE–34).

OMB No.: 0970–0181.

Description: State and Tribal agencies administering the Child Support Enforcement Program under Title IV–D of the Social Security Act are required to provide information each fiscal quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents. State title IV–D agencies report quarterly expenditures and collections using Forms OCSE–396 and OCSE–34, respectively. Tribal title IV–D agencies report quarterly expenditures using Form SF–425, as prescribed in program regulations, and formerly reported quarterly collections using only a modified version of Form OCSE–34. The information collected on these reporting forms is used to compute quarterly grant awards to States, the annual incentive payments to States, and provides valuable information on program finances of States and Tribes. The collected information is also included in a published annual statistical and financial report, available to the general public.

In response to an earlier **Federal Register** Notice (77 FR 72352 December, 2012), this agency received comments to support the minor changes and revisions to these forms at this time. As we continued to discuss improvements to these reporting forms with State and Tribal grantees we list a few minor revisions that have been incorporated to facilitate grant award operations and grantee financial reporting. These revisions were limited to any changes that allow Tribal grantees to, at least, use the same quarterly collection report submitted by State grantees. Additionally, further clarification was provided to reduce confusion over the inclusion of the Federal share of funding in computations of claims and to standardize treatment of claims. Finally, there were minor revisions in the title of the forms by reverting to the original designation as Form OCSE–396 and Form OCSE–34 and minor changes to the existing wording to improve clarity and accuracy.

One respondent was concerned with the Tribal and State governments using the same OCSE–34 Form, which was perceived to lead to an added burden and confusion about the submission of specific data elements. Our sense is that the form is developed in a sufficiently clear manner to inform respondents on the data elements required by each type of grantee. Furthermore, we consistently provide outreach and technical assistance to all grantees to ensure that reporting burdens are clear and minimized.

A few respondents provided technical and clerical edits to the OCSE–396 Form to increase accuracy and clarity. We have incorporated many of the requested edits and appreciate the detailed and thoughtful comments.

One respondent was concerned that the instructions to the OCSE–396 may be creating an additional burden by maintaining a 5 percent variance threshold (an increase or decease in any data element of Part 1 compared to that same data element for the previous quarter). While we are understanding of this concern our position is that the form will be used nationally and raising the variance threshold above 5 percent is not justified at this time.

Respondents: State and Tribal agencies (including New York, Texas, Washington, Puyallup Tribe, and Port Gamble S'klallam Tribe) administering a Child Support Enforcement Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396	54	4	6	1,296
OCSE–34	114	4	14	6,384

Estimated Total Annual Burden Hours: 7,680.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF 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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–04192 Filed 2–25–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2013.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Committee Management Officer, Advisory Committee and Oversight Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8220.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2012, through September 30, 2013:

Center for Biologics Evaluation and Research

Blood Products Advisory Committee, Cellular, Tissue, and Gene Therapies Advisory Committee, Vaccines and Related Biological Products Advisory Committee.

National Center for Toxicological Research

Science Board to the National Center for Toxicological Research.

Center for Tobacco Products

Tobacco Products Scientific Advisory Committee.

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

(1) The Library of Congress, 101 Independence Ave. SE., James Madison Memorial Bldg., Newspaper and Current Periodical Reading Room, Rm. 133, Washington, DC 20540; and

(2) The Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 21, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–04144 Filed 2–25–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0811]

Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat Clostridium difficile Infection Not Responsive to Standard Therapies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,'' dated March 2014. This draft guidance informs members of the medical and scientific community and other interested persons that we intend to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat *C. difficile* infection not responding to standard therapies, provided the licensed health care provider treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for use of the FMT products, the stool is obtained from a donor known to either the patient or the licensed health care provider treating the patient, and the donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product to treat his or her patient. This draft guidance, when finalized, is intended to supersede the guidance document entitled ''Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,'' dated July 2013 (July 2013 Guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 28, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written

comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,'' dated March 2014.

Fecal microbiota collected from healthy individuals are being investigated for use in the treatment of *C. difficile* infection that is not responsive to standard therapies. Published data suggest that the use of fecal microbiota to restore intestinal flora may be an effective therapy in the management of refractory *C. difficile* infection. However, the efficacy and safety profile of this intervention has not yet been fully evaluated in controlled clinical trials.

In the **Federal Register** of July 18, 2013 (78 FR 42965), FDA announced the availability of the July 2013 Guidance. At that time, FDA informed members of the medical and scientific community, and other interested persons that it intended to exercise enforcement discretion regarding these requirements provided that the physician treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products. FDA received several comments on the guidance, all of which supported enforcement discretion with regard to the continued use of FMT products to treat *C. difficile* infection not responsive to standard therapies.

Since publishing the July 2013 Guidance, FDA has reviewed and intends to modify its enforcement discretion policy. In this draft guidance, FDA explains that it intends to exercise enforcement discretion regarding the IND requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies provided that: (1) The licensed health care provider treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for the use of FMT products; (2) the FMT product is obtained from a donor known to either the patient or the licensed health care provider treating the patient; and (3) the stool donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product to treat his or her patient. This policy does not extend to the use of an FMT product when the FMT product is manufactured from the stool of a donor who is not known by the patient and/or the licensed health care provider treating the patient, or the donor and donor stool are not qualified under the direction of the licensed health care provider. Furthermore, this policy does not extend to other uses of FMT. Data related to the use and study of FMT to treat diseases or conditions other than *C. difficile* infection are limited, and study of FMT for these other uses is not included in this enforcement policy.

FDA intends to exercise this discretion on an interim basis while the Agency further considers the matter, and continues to evaluate its enforcement policy. The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04095 Filed 2–25–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Food and Drug Administration/Xavier University Global Medical Device Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University Global Medical Device Conference (MedCon).'' This 3-day public conference includes presentations from key FDA officials and industry experts with small group breakout sessions. The conference is intended for companies of all sizes and employees at all levels.

Dates and Times: The public conference will be held on May 7, 2014, from 8:30 a.m. to 5 p.m.; May 8, 2014, from 8:30 a.m. to 5 p.m.; and May 9, 2014, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3020.

Contact Persons: For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, FAX: 513–679–2771, email: *gina.brackett@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073, email: *phillipsm4@xavier.edu.*

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, and lunches for the 3 days of the conference. Early registration ends March 11, 2014. Advanced registration rates begin March 12, 2014. Standard registration rates begin April 9, 2014. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee Type	Early rate (through 3/11/14)	Advanced rate (3/12/14 to 4/8/14)	Standard rate (4/9/14 to 5/9/14)
Industry	$1,195	$1,495	$1,695
Small Business (<100 employees)	$900	$1,000	$1,200
Startup Manufacturer	$200	$250	$300
Academic	$200	$250	$300
FDA/Government Employee	Fee Waived	Fee Waived	Fee Waived.

[1] The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierMedCon.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Mason Rick, 3800 Victory Parkway, Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH, 45202, 513–421–9100. Special conference block rates are available through April 16, 2014. To make reservations online, please visit the ''Venue/Logistics'' link at *http://www.XavierMedCon.com.*

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- Center for Devices and Radiological Health Future Vision and Strategy Keynote Address;
- European Union Regulations: New Regulations, Company Strategy, and Open Discussion Forum;
- How to Implement the Unique Device Identification Requirements;
- Update from the Office of Device Evaluation;
- FDA Regulation of Health Information Technology: Medical Apps, Cybersecurity, and ''the Cloud'';
- Managing Scientific and Regulatory Disagreement;
- Combination Products;
- FDA Inspectional Approach—Panel with current FDA investigators;
- Operationalizing Post-Market Surveillance;
- 510(k) Process;
- Risk Management;
- Purchasing Controls;
- Office of Compliance Update; and
- Strategic Thinking on Access in China.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04134 Filed 2–25–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; National Institute of Mental Health Recruitment and Milestone Reporting System

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 2, 2013, page 46994 and allowed 60-days for public comment. One public comment was received regarding human subjects research recruitment and retention and the perception of coercion. The recruitment and enrollment procedures proposed by a NIMH-funded clinical trial are reviewed and approved by an IRB of record, which has agreed to review human subject research projects in accordance with 45 CFR Part 46 and its Federal-wide Assurance. The IRB of record ensures that the possibility of coercion or undue influence is minimized, that an investigator seeks consent only under circumstances that provide the prospective subject/representative sufficient opportunity to consider whether or not to participate. To address these concerns, we plan to add a statement about human subject protections to the policy and add a link to the human subjects training on the policy Web page. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667,

Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection

National Institute of Mental Health Recruitment Milestone Reporting System-Existing collection in use without OMB control number—National Institute of Mental Health (NIMH), National Institute of Health (NIH).

Need and Use of Information Collection: The Recruitment Milestone Reporting (RMR) System allows NIMH staff to monitor more accurately the recruitment of participants in NIMH-sponsored clinical research studies that plan to enroll 150 or more human subjects in a single study. Clinical studies can have difficulty recruiting, and accurate and timely reporting is the best way to ensure proper use of the grant funds. Investigators develop a recruitment plan that includes tri-yearly milestones for recruitment of the total study population, and for recruitment of racial and ethnic minority participants. Once recruitment is scheduled to begin, investigators report actual progress on recruitment milestones three times per year, by April 1, August 1, and December 1. The primary use of this information is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research. By ensuring timely recruitment into clinical research studies, NIMH can reduce the need to extend timelines or supplement funds in order to complete the research project, and potentially increase efficiency in our funding process.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,531.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average burden per response (in hours)	Total annual burden hours
NIMH Recruitment Milestone Reporting.	Principal Investigators/Research Assistant.	675	3	75/60	2,531

Dated: February 18, 2014.

Keisha Shropshire,

Project Clearance Officer, NIMH, NIH.

[FR Doc. 2014–04194 Filed 2–25–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel Drug Development for Alzheimer's Disease.

Date: March 19, 2014.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Room 2C212, Gateway Building, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute On Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel, Genetic Factors.

Date: March 26, 2014.

Time: 12:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alicja L. Markowska, Ph.D., DSC, Scientific Review Branch, National Institute On Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 20, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–04082 Filed 2–25–14; 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 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 Allergy and Infectious Diseases Special Emphasis Panel NIAID Investigator Initiated Program Project Applications (P01).

Date: March 13, 2014.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3254, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Susana Mendez, Ph.D., DVM, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC–7616,

Bethesda, MD 20892–7616, 301–496–2550, *mendezs@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Sexually Transmitted Infections Cooperative Research Centers (STI CRC) (U19).

Date: March 17–18, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Maryam Feili-Hariri, 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, 301–594–3243, *haririmf@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Peer Review.

Date: March 18, 2014.

Time: 1:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 3201B, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Travis J Taylor, Ph.D., Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700–B Rockledge, Dr. MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, *Travis.Taylor@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Investigator Initiated Program Project Applications (PO1).

Date: March 20, 2014.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3254, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Susana Mendez, Ph.D., DVM, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, *mendezs@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: February 20, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–04081 Filed 2–25–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival.

Date: February 27, 2014.

Time: 3:00 p.m. to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, *wieschd@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13–109: Mechanistic Insights from Birth Cohorts.

Date: February 28, 2014.

Time: 12:00 p.m. to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery and Molecular Pharmacology.

Date: March 4, 2014.

Time: 1:00 p.m. to 2:00 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–594–7945, *smileyja@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 20, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–04079 Filed 2–25–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2012–0632]

RIN 1625–AA11

Regulated Navigation Area: Buzzard's Bay, MA; Navigable Waterways Within the First Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of Availability.

SUMMARY: The Coast Guard is issuing this notice to advise the public that we have prepared a Finding of No Significant Impact (FONSI) based on the Final Environmental Assessment (Final EA) for the amendments to the Buzzards Bay Regulated Navigation Area that were implemented in 2007. The Coast Guard prepared the Final EA, dated December 2013, in accordance with the National Environmental Policy Act (NEPA) and the Coast Guard's Agency procedures for implementing NEPA.

DATES: The FONSI and Final EA are available as of the publication date of this notice.

FOR FURTHER INFORMATION CONTACT: Mr. John Mauro, Coast Guard First District Waterways Management Branch, telephone 617–223–8355, email *John.J.Mauro@uscg.mil* or Mr. Luke Dlhopolsky, Civil Engineering Unit, Environmental Protection Specialist, telephone 401–736–1743, email *Lucas.A.Dlhopolsky@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Final EA evaluates the existing Regulated Navigation Area (RNA) applicable to First Coast Guard District waters as it was amended in 2007 (the ''2007 Final Rule'') (72 FR 50052; corrected by 72 FR 70780). The purpose of those amendments was to enhance the pre-2007 RNA by adding measures intended to further reduce the probability of an incident that could result in the discharge or release of oil or hazardous material, or cause serious harm, to navigable waters of the United States. As part of the process to implement the 2007 Final Rule, the USCG prepared a Categorical Exclusion Determination as defined in its Agency Procedures for Implementing the National Environmental Policy Act. In a ruling on May 17, 2011, the 1st U.S. Circuit Court of Appeals determined that the USCG ''failed to comply with its obligations under the National Environmental Policy Act'' when it failed to prepare an Environmental Impact Statement (EIS) or an Environmental Assessment (EA). This Final EA is intended to remedy that insufficiency.

Dated: February 4, 2014.

D.B. Abel,

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

[FR Doc. 2014–04176 Filed 2–25–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5759–N–05]

60-Day Notice of Proposed Information Collection: Promise Zones

AGENCY: Office of 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:* April 28, 2014.

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 202–402–5564 (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 through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Promise Zones.

OMB Approval Number: 2577–0279.

Type of Request: Revision of a currently approved collection.

Form Number: Pending Assignment.

Description of the need for the information and proposed use: Under the Promise Zones initiative, the federal government will invest and partner with high-poverty urban, rural, and tribal communities to create jobs, increase economic activity, improve educational opportunities, leverage private investment, and reduce violent crime. Additional information about the Promise Zones initiative can be found at *www.hud.gov/promisezones*, and questions can be addressed to *promisezones@hud.gov*. This notice estimates burden for applying for the designation.

Respondents (i.e. affected public): Local or Tribal Governments.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Abstract	300	1	1	3	900	$40	$36,000
Qualifying Criteria/Need Narrative	300	1	1	3	900	40	36,000
Local leadership support—Documentation	300	1	1	4	1200	40	48,000
Need—Poverty rate	300	1	1	1	300	40	12,000
Need—Crime rate	300	1	1	3	900	40	36,000
Need—Employment rate	300	1	1	1	300	40	12,000
Need—Vacancy rate	300	1	1	1	300	40	12,000
Strategy—Community Assets and Neighborhood Position, Mapping	300	1	1	6	1800	40	72,000
Strategy—Narrative and Template	300	1	1	10	3000	40	120,000
Strategy—Sustainability and financial feasibility	300	1	1	5	1500	40	60,000
Capacity—Lead documentation	300	1	1	3	900	40	36,000
Capacity—Partner documentation	300	1	1	4	1200	40	48,000

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Capacity—Partner Organization Chart	300	1	1	3	900	40	36,000
Capacity—Local government	300	1	1	3	900	40	36,000
Capacity—Partnership commitments documentation	300	1	1	10	3000	40	120,000
Total	300	1	1	60	18000	40	720,000

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: February 19, 2014.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2014–04200 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5756–N–05]

60-Day Notice of Proposed Information Collection: Quality Control Requirements for Direct Endorsement Lenders

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: *Comments Due Date:* April 28, 2014.

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: Justin D. Burch, Director, Quality Assurance Division, Office of Lender Activities and Program Compliance, Department of Housing and Urban Development, 451 7th Street SW., Room B133–P3214, Washington, DC 20410, telephone 202–708–1515 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Mr. Burch.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Quality Control Requirements for Direct Endorsement Lenders.

OMB Approval Number: 2502–0600.

Type of Request: Extension of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: Under 24 CFR 202.8(3), Direct Endorsement (DE) lenders which sponsor third-party originators (TPOs) are responsible to the Secretary for the actions of TPOs or mortgagees in originating loans or mortgages, unless applicable law or regulation requires specific knowledge on the part of the party to be held responsible. As a result, DE lenders are responsible for conducting quality control on TPO originations of FHA-insured mortgage loans, and ensuring that their quality control plans contain appropriate oversight provisions. This creates an information collection burden on DE lenders, since these institutions must conduct quality control on all loans they originate and underwrite. In addition, under 24 CFR 203.255(c) and (e), HUD conducts both pre- and post-endorsement reviews of loans submitted for FHA insurance by DE lenders. As part of those reviews, the Secretary is authorized to determine if there is any information indicating that any certification or required document is false, misleading, or constitutes fraud or misrepresentation on the part of any party, or that the mortgage fails to meet a statutory or regulatory requirement. In order to assist the Secretary with this directive, FHA requires that lenders self-report all findings of fraud and material misrepresentation, as well any material findings concerning the origination, underwriting, or servicing of the loan that the lender is unable to mitigate or otherwise resolve. The obligation to self-report these findings creates an additional information collection burden on DE lenders.

In accordance with the requirements of 5 CFR 1320.8(d), a Notice soliciting comments on this collection of information was initially published in the **Federal Register** on December 21, 2010 (Volume 75, Number 244, page 80066). At that time, FHA still allowed for loan correspondents to participate in its programs and had not yet transitioned to the use of TPOs. Therefore, FHA estimated information

collection burdens based on the expected used of TPOs by DE lenders. Three years later, FHA has revised these estimates with real data, which has substantially reduced the information collection burden associated with OMB Control Number 2502–0600.

Respondents: Business or other for-profit

Estimated Number of Respondents: 1,831.

Estimated Number of Responses: 135,682.

Frequency of Response: Annually.

Average Hours per Response: .52.

Total Estimated Burdens: 71,017.

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: February 20, 2014.

Laura M. Marin,

Associate General Deputy Assistant Secretary for Housing-Associate Deputy Federal Housing Commissioner.

[FR Doc. 2014–04198 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5752–N–23]

30-Day Notice of Proposed Information Collection: Capital Fund Community and Education Training Facilities

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* March 28, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 18, 2013.

A. Overview of Information Collection

Title of Information Collection: Capital Fund Community and Education Training Facilities.

OMB Approval Number: 2577–0268.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–27061, HUD–50075.1.

Description of the need for the information and proposed use: The Department of Housing and Urban Development awarded grant funds to 19 Public Housing Authorities (PHAs) in 2010 and 2011 for the development of facilities to provide early childhood education, adult education, and/or job training programs for public housing residents based on an identified need. These facilities will offer comprehensive, integrated supportive services to help public housing residents achieve better educational and economic outcomes resulting in long-term economic self-sufficiency. This collection of information will enable HUD to determine if the PHAs are making efficient use of the funds awarded.

Respondents (i.e. affected public): Individuals or households, State, Local, or Tribal Government.

Estimated Annual Reporting and Recordkeeping Burden:

Form/document	Number of respondents	Frequency	Total responses	Hours per response	Total hours	Cost per hour	Total cost
1 Two-page summary of development activity	19	1	19	.5	9.5	$40.58	$385.50
2 HUD–27061	19	1	19	0.25	4.75	40.58	192.75
3 HUD–50075.1	19	1	19	0.25	4.75	40.58	192.75
Totals			19	1.00	19		771.00

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. Chapters 35.

Dated: February 20, 2014.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2014–04201 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5752–N–12]

30-Day Notice of Proposed Information Collection: Exigent Health and Safety Deficiency Correction Certification

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* March 28, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA__Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 26, 2013.

A. Overview of Information Collection

Title of Information Collection: Exigent Health and Safety Deficiency Correction Certification.

OMB Approval Number: 2577–0241.

Type of Request: Extension of a currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: HUD's Uniform Physical Condition Standards (UPCS) regulation (24 CFR part 5, subpart G) provides that HUD housing must be decent, safe, sanitary, and in good repair. The UPCS regulation also provides that all area and components of the housing must be free of health and safety hazards. HUD conducts physical inspections of the HUD-funded housing to determine if the UPCS standards are being met. Pursuant to the UPCS inspection protocol, at the end of the inspection (or at the end of each day of a multi-day inspection) the inspector provides the property representative with a copy of the ''Notification of Exigent and Fire Safety Hazards Observed'' form. Each exigent health and safety (EHS) deficiency that the inspector observed that day is listed on the form. The property representative signs the form acknowledging receipt. PHAs are to correct/remedy/act abate all EHS deficiencies within 24 hours. Using the electronic format, PHAs are to notify HUD within three business days of the date of inspection, which is the date the PHA was provided notice of these deficiencies, that the deficiencies were corrected/remedied/acted on to abate within the prescribed time frames (24 CFR part 902).

Respondents (i.e. affected public): Public Housing Agencies.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	1134	1	1	0.31	346.29	$8.82	$10,000.86

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. Chapters 35.

Dated: February 20, 2014.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2014–04199 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5800–N–01]

Notice of HUD's Fiscal Year (FY) 2014 Notice of Funding Availability (NOFA) Policy Requirements and General Section to HUD's FY 2014 NOFAs for Discretionary Programs

AGENCY: Office of Strategic Planning and Management, HUD.

ACTION: Notice of HUD's FY2014 NOFA Policy Requirements and General Section to HUD's FY2014 NOFAs for Discretionary Grant Programs.

SUMMARY: This notice announces that HUD has posted on *http://www.Grants.gov* and *http://www.HUD.gov* its FY 2014 General

Section to the Department's FY 2014 NOFAs for Discretionary Programs (General Section). HUD's General Section contains submission and other cross-cutting requirements applicable to all of FY 2014 HUD's competitive funding opportunities (NOFAs). In addition, the General Section lists HUD's Strategic Goals and NOFA priorities that HUD will use in FY 2014.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Planning and Management, Grants Management Division, Department of Housing and Urban Development, 451 Seventh Street SW., Room 3156, Washington, DC 20410–3000; telephone number 202–708–0667, or email *loyd.lamois@hud.gov* or *dorthera.yorkshire@hud.gov*. 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.

SUPPLEMENTARY INFORMATION: Today's **Federal Register** notice announces that HUD has posted its FY 2014 General Section on *http://www.Grants.gov* and *http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/grants/fundsavail.* The General Section describes the requirements that are applicable to all of HUD FY 2014 Discretionary Program NOFAs.

The General Section also provides summary information regarding HUD's Strategic Goals and FY 2014 NOFA priorities. HUD encourages applicants for funding in FY2014 to undertake programs and projects that contribute to HUD's strategic goals and NOFA priorities. HUD's NOFA priorities are designed to align grantee efforts with HUD's Strategic Goals and the Department's Mission. Applicants that undertake activities that result in achievement of specific NOFA priorities are eligible to receive priority points in the rating of their application.

Each program NOFA will describe additional procedures and requirements that apply to the individual program, including a description of the eligible applicants, eligible activities, threshold requirements, cross-program requirements such as nondiscrimination, environmental protection, and any additional program requirements or limitations. To adequately address all of the application requirements for any program, HUD encourages potential applicants to carefully read and respond to both the General Section and the applicable Program NOFA. NOFA priority points will be considered only if the application already meets or exceeds the NOFA's threshold for funding.

HUD will post its FY 2014 program NOFAs on *http://www.Grants.gov* and *http://www.HUD.gov* as they become available. Today's notice is intended to provide prospective applicants for HUD's competitive funding with the opportunity to become familiar with the General Section of HUD's FY2014 NOFAs, in advance of publication of any FY2014 NOFAs.

Dated: February 21, 2014.

Henry Hensley,

Acting Director, Office of Strategic Planning and Management.

[FR Doc. 2014–04205 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5763–N–02]

Privacy Act; Notification of a New Privacy Act System of Records, Homeless Families Impact Study Data Files

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice of Proposed Revision of an Existing System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Department of Housing and Urban Development, gives notice of a proposed revision of an existing Privacy Act system of records. The system of records is being updated to allow the Department to conduct a follow-up evaluation on the participants of the Homeless Families Impact Study. Additionally, the Department proposes to expand the data collected under the previous study to capture additional data to determine the effects that housing and service interventions has had on participating children. Refer to the ''Categories of Records'' caption to identify new record types. The overall goal of this study is to determine which intervention works best to promote housing stability, family preservation, and family well-being, and self-sufficiency for homeless families. This notice supersedes the previously published notice (October 4, 2010, 75 FR 24750).

COMMENTS DUE DATE: March 28, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Donna Robinson-Staton, Departmental Privacy Act Officer, 451 Seventh Street SW., Room 2256, Washington, DC 20410, Telephone Number (202) 402–8047. (This is not a toll-free number.) A telecommunication device for hearing- and speech-impaired individuals (TTY) is available at (800) 877–8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended notice is given that HUD proposes to establish a revised system of records as identified as Homeless Families Impact Study Data Files.

Title 5 U.S.C. 552a(e)(4) and (11) provide that the public be afforded a 30-day period in which to comment on the new system of records.

The revised system report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Governmental Affairs, and the House Committee on Government Reform pursuant to paragraph 4c of Appendix 1 to OMB Circular No. A–130, ''Federal Responsibilities for Maintaining Records About Individuals,'' July 25, 1994 (59 FR 37914).

Authority: 5 U.S.C. 552a 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: February 12, 2014.

Kevin R. Cooke, Jr.,

Acting Chief Information Officer.

PD&R/RRE.03

SYSTEM NAME:

Homeless Families Impact Study Data Files.

SYSTEM LOCATION:

Homeless Families Impact Study Data Files are to be located at Abt Associates Inc., 55 Wheeler Street, Cambridge, MA; Abt Associates Inc., 4550 Montgomery Avenue, Bethesda, MD; and the AT&T Datacenter, 15 Enterprise Ave, Secaucus, NJ 07094. U.S. Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Families enrolled in Homeless Families Impact Study (also known as the Family Options Study).

CATEGORIES OF RECORDS IN THE SYSTEM:

Name; Social Security Number; study identifier; birth date; contact information (home address, telephone numbers, email address); demographic characteristics of the family head (e.g., race/ethnicity, gender, marital status); number of children and other adults in the household (a roster of adults and children with the family head at baseline and spouse/partner and children not with the family head at baseline, and characteristics of these family members); income sources and total family income; employment and earnings for the family head; health (behavioral health and physical health of the family head); substance use; foster care history for the family head; exposure to domestic violence; housing status prior to shelter entry; homelessness history; barriers to housing; homeless program participation; contact information for family and friends; and assigned study intervention, and study involvement information. The revised system, to be effective as of March 2014, will expand the categories of records to include: instances of family separation and reunification; foster care placements of children during the follow-up period; food insecurity; economic well-being (economic stressors and financial stability); parenting practices; family routines; home environment; program service participation and experiences; child well-being (including: child behavioral health, child physical health, school engagement, child development, child executive functioning, risky behaviors of older youth, and child academic performance).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sec. 501, 502, Housing and Urban Development Act of 1970 (Pub.L. 91–609), 12 U.S.C. 1701z–1, 1701z–2.

PURPOSE:

The U.S. Department of Housing and Urban Development (HUD) is undertaking an evaluation of the Impacts of Housing and Services Interventions for Homeless Families, also known as the Family Options Study, to provide research evidence to help federal policymakers, community planners, and local practitioners make sound decisions about the best ways to address homelessness among families. This study will compare four combinations of housing and service interventions for homeless families in a rigorous, multi-site experiment, to determine what interventions work best to promote family stability and well-being and, within the limits of statistical power, what sorts of families benefit most from each intervention. The interventions are: (1) Permanent housing subsidy without services (Subsidy Only); (2) Community-Based Rapid Re-housing (CBRR), consisting of temporary housing subsidy provided in conventional housing with limited supportive services; (3) temporary housing subsidy provided in facility-based housing with intensive services but no guarantee of a permanent subsidy (Project-Based Transitional Housing-PBTH); and (4) shelter, with whatever services the shelter ordinarily provides to its residents and any other assistance available in the community (Usual Care). The information collected is necessary to identify and track the participating families over the course of the study and determine the effectiveness of the interventions. The random assignment data file within this system will include personal identifiers that can be used to locate records to update families' whereabouts or to verify if a family has already been enrolled in the study. After data collection is complete, researchers will use a dataset that is stripped of identifying information for all analyses. Analysis records will be identified with a randomly generated study identification number that is unrelated to personal information such as SSN, DOB, or name. The study identifier can be linked to the personal identifying information only by a small number of central research staff at Abt Associates. At the end of the 36-month follow-up, HUD staff will be provided with the identifiers only for families who gave consent to participate in the 36-month follow-up. Thus, authorized HUD research staff would also be able to link the study identifier to personal identifying information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

- To authorized Abt SRBI researchers to match primary study data with other datasets for tracking (e.g., matching with change of address databases) to track and locate families throughout the study and to manage the data collection process.
- To authorized Abt researchers to: (1) Access and link data from one phase of data collection to another or to match primary study data with other datasets for data collection purposes (e.g., matching with HUD's public housing dataset to measure housing receipt); (2) perform statistical Analysis and to develop findings for this research study; (3) and Create both a public use file of non-identifiable data and a more-detailed restricted access file of non-identifiable data for disclosure to authorized researchers for other purposes.
- To other authorized HUD researchers that HUD funds to further study the impacts of the housing and services interventions that are the focus of this study (community based rapid rehousing, project-based transitional housing, permanent subsidy and usual care) and additional ways each can be used to address homelessness.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic Records: Backup media is stored in a commercial locked facility and the media is transported using locked, tracked containers. Unencrypted data will never be stored on a laptop or on a movable media such as CDs, diskettes, or USB flash drives. *Paper Records:* All hard copy forms with personal identifying data (the participant agreement/informed consent form) will be stored securely in a locked cabinet that can only be accessed by authorized individuals working on the data. The locked cabinet will be stored in a locked office in a limited-access building. While in the field, paper records will be stored securely until they are processed and securely sent to Abt Associates via commercial mail carrier.

RETRIEVABILITY:

Records within the random assignment data file can be retrieved by name, social security number, study identification number, birthdate, or spouse name.

SAFEGUARDS:

The following safeguards shall be used to secure data in storage, retrieval, during access, and disposal. *For Electronic Records:* All personal data will be maintained on a secure workstation or server that is protected by a firewall and complex passwords in a directory that can only be accessed by the network administrators and the analysts actively working on the data; access rights to the data are granted to limited researchers on a need-to-know basis, and the level of access provided to each researcher is based on the minimal level required that individual to fulfill his research role; all systems used to process or store data have Federal security controls applied to them; the data will be backed up on a regular basis to safeguard against system failures or disasters; and, unencrypted data will never be stored on a laptop or on a movable media such as CDs,

diskettes, or USB flash drives. *For Paper Records:* The site interviewers will securely store any hard copy forms with personal identifiers until they are shipped to Abt Associates via commercial mail services; all hard copy forms with personal identifying data (the participant agreement/informed consent form) will be stored securely in a locked cabinet that can only be accessed by authorized individuals working on the data. The locked cabinet will be stored in a locked office in a limited-access building. Additionally, permissions will be defined for each authorized user based on the user's role on the project. For example, the local site interviewer will be able to review data for study participants only for his or her own specific site. Study data will be aggregated or de-identified at the highest level possible for each required, authorized use. Abt Associates and HUD will not use or disclose the data for any purposes other than for the ''The Impacts of Housing and Services Interventions for Homeless Families'' study (''Family Options Study'') or other purposes described above and specified in the consent with participating families. Abt Associates, HUD, and other authorized users will not disclose the data to additional parties without the written authority of the participating families or providing organizations, except where required by law.

RETENTION AND DISPOSAL:

The retention and disposal procedures are in keeping with HUD's records management policies as described in 44 U.S.C. 3101 and 44 U.S.C. 3303. All PII associated with the project will be destroyed by Abt, Abt SRBI and HUD or otherwise rendered irrecoverable per NIST SP 800–88 ''Guidelines for Media Sanitization'' (September 2006). The data may remain on backup media for a longer period of time, but will be similarly permanently destroyed at the end of the three-year retention period required in the contract.

SYSTEM MANAGER(S) AND ADDRESS:

Carol Star, Director of the Program Evaluation Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, Telephone Number (202) 402–6139.

NOTIFICATION AND RECORD ACCESS PROCEDURE:

For information, assistance, or inquiry about existence or records, contact Donna Robinson-Stanton, Chief Privacy Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC, in accordance with the procedures in 24 CFR part 16. The Department's rules for providing access to records to the individual concerned appear in 24 CFR parts 16. If additional information or assistance is required, contact the Privacy Act Officer at the appropriate location. The data collected for inclusion in this system of records is also protected by a federal Certificate of Confidentiality issued by the National Institute of Child Health and Human Development (NICHD). This certificate protects the data from being released under Freedom of Information Act requests and subpoena.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting the contents of records and appealing initial denials, by the individual concerned, appear in 24 CFR part 16. If additional information or assistance is needed, it may be obtained by contacting:

(i) In relation to contesting contents of records, the Departmental Privacy Act, Department of Housing and Urban Development, 451 Seventh Street SW., Room 2256, Washington, DC 20410, or

(ii) In relation to appeals of initial denials, the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Original data collected directly from participating families, third party data for tracking purposes (e.g. National Change of Address database, credit bureaus), administrative data on HUD's public housing programs, and non-HUD administrative data such as the Adoption and Foster Care Analysis and Reporting System (AFCARS) data and individual-level data on earnings, wages and the receipt of unemployment insurance.

EXEMPTION FROM CERTAIN OF PROVISION OF THE ACT:

None.

[FR Doc. 2014–04202 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5763–N–01]

Implementation of the Privacy Act of 1974, as Amended; Republication To Delete and Update Privacy Act System of Records Notifications

AGENCY: Office of the Chief Information Officer.

ACTION: Notice Republications.

SUMMARY: Pursuant to the Privacy Act of 1974 (U.S.C. 552a (e) (4)), as amended, and Office of Management and Budget (OMB), Circular No. A–130, notice is hereby given that the Department of Housing and Urban Development (HUD), Office of the Chief Information Officer (OCIO) republishes in the **Federal Register** actions for 12 program component systems of records. The revisions implemented under this republication are corrective and administrative that refines previously published details for each system of records in a clear and cohesive format. This republication does not meet the threshold criteria established by the Office of Management and Budget (OMB) for a modified system of records report. A more detail descriptions of the present systems are republished under this notice. This notice supersedes all previously published notices.

DATES: *Effective Date:* All revisions included in this republication are complete and accurate as of [January 23, 2014].

FOR FURTHER INFORMATION CONTACT: Donna Robinson-Staton, Chief Privacy Officer, 451 Seventh Street SW., Washington, DC 20410 (Attention: Capitol View Building, 4th Floor), telephone number: (202) 402–8073. [The above telephone number is not a toll free numbers.] A telecommunications device for hearing- and speech-impaired persons (TTY) is available by calling the Federal Information Relay Service's toll-free telephone number (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Republication To Delete and Update Privacy Act Systems of Records

Subsequent reviews for 12 systems of records resulted in an update to 3 systems of records and a deletion of 9 systems of records. Final analysis concluded with removing obsolete documentation from the Department's system of records repository, refining categories of information and republishing information in a clear and cohesive format, and implementing new coding schemes for each systems of records, in an effort to streamline and present each system of records in a coding structure that easily differentiate program specific systems of records. These notices were last published in the **Federal Register** under separate citations. The **Federal Register** publications and citations associated

with each notice can be viewed by going to the Department's Privacy Web site.[1]

Deleted Systems—The 9 systems deleted by this republication, and their existing coding structure are listed as follows:

1. HUD/H–3 Single Family Housing Monitoring System
2. HUD/H–8 Property Rental Files
3. HUD/DEPT–20 Single Family Homeownership Assistance Application and Recertification (HARAS)
4. HUD/DEPT–22 Housing Counseling, April 22, 1982
5. HUD/DEPT–23 Single-Family Research Files
6. HUD/DEPT–43 Real Estate owned (REO) Property Files
7. HUD/DEPT–32 Mortgages—Delinquent/Default/Assigned/Temporary Mortgage Assistance Payments [TMAP] Program
8. HUD/HS–57 (A80N)—Single Family Mortgage Notes System
9. HUD/HS–60 Nonprofit Data Management System (NPDMS) System

Updated Systems—This following notices supersede the previously published notices. The 3 systems modified by this republication and their new coding structure are listed as follows:

1. HSNG.SF/HWAA.01 Single Family Acquired Asset Management System (Previously SAMS A80s, published June 20, 2006)
2. HSNG.SF/HWAA.02 Single Family Insurance System CLAIMS Subsystem (HUD/SFH–02, Published November 20, 2007)
3. HSNG.SF/HUF.01 Asset Disposition and Management System (Previously HUD/HS–58, Published October 21, 2008)

These systems are those maintained by HUD that included or includes personally identifiable information provided by individuals from which information was or is retrieved by a name of unique identifier. The system revisions encompass programs and services of the Department's data collection and management practices. Under this republication, the Department proposes to update 3 Privacy Act systems of records, and delete 9 obsolete systems of records, and implement a new coding structure for updated systems of records.

This republication allows HUD to organize and re-publish up-to-date information for these systems of records in a more useful format. The system modifications and deletions incorporate Federal privacy requirements, and HUD policy requirements. The Privacy Act provides certain safeguards for an individual against and invasion of personal privacy by requiring Federal agencies to protect records contained in an agency system of records from unauthorized disclosure, ensure that information is current for its intended use, and that adequate safeguards are provided to prevent misuse of such information. Additionally, the updates reflect the Department's focus on industry best practices in protecting the personal privacy of the individuals covered by each system notification. This notice for each system of records state the name and location of the record system, the authority for and manner of it operations, the categories of individuals that it covers, the type of records that it contain, the sources of the information for those records, the routines uses of each systems of records, and the system of records exemption types. In addition, each notice include the business address of the HUD officials who will inform interested persons of the procedures whereby they may gain access to and/or request amendments to records pertaining to them. The routine uses that apply to this publication are reiterated based on past publication to clearly communicate the ways in which HUD continues to conducts some of its business practices.

Since the republication of system of records notices does not meet the threshold requirements for new or amended system a report was not submitted to the Office of Management and Budget (OMB), the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Government Reform as instructed by Paragraph 4c of Appendix l to OMB Circular No. A–130, ''Federal Agencies Responsibilities for Maintaining Records About Individuals,'' July 25, 1994 (59 FR 37914).

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: February 21, 2014.

Joseph Milazzo,

Deputy Chief Information Officer.

HSNG.SF/HWAA.01

SYSTEM NAME:

Single Family Acquired Asset Management System.

SYSTEM LOCATION:

2020 Union Carbide Drive, South Charleston, WV 25303–2734, and at the HUD Headquarters building, 451 Seventh Street SW., Washington, DC 20410.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are covered by this system include successful bidders of a HUD-owned property. Also, individuals involved in the sale of HUD/FHA Single-Family homes: Management and Marketing contractors (M&M), HUD employees, Brokers, and Contractors.

CATEGORIES OF RECORD IN THE SYSTEM:

Files contain identifying information about: Purchasers, such as name, Social Security Number, and current address. HUD Employees, such as Headquarters and Homeownership staff, Brokers, such as Selling Brokers and Closing Agents, Contractors, such as Management and Marketing (M&M) contractors: Mortgagee Compliance Monitor, Asset Managers and Field Service Managers,Vendors, such as appraisers, trade/service vendors, homeowner associations, local/state governments, nonprofit organizations, NSP grantees. In addition, the files contain: HUD–1 information, such as appraisal information, tax payments, sales offer information, contract information, and accounting transactions, 1099 information, such as payees (except tax-exempt organizations) who receive $600.00 or more during a single tax year for services provided to HUD,

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Housing Act as amended (12 U.S.C. 1702 et seq.). HUD is authorized to collect the Social Security Number (SSN) by Section 165(a) of the Housing and Community Development Act of 1987, Public Law 100–242 and by 42 U.S.C. 3543.

PURPOSE:

SAMS is a management and accounting system for HUD owned and HUD managed single-family properties. The re-engineered application was introduced into production in 1996. SAMS supports HUD staff at Headquarters and Homeownership Centers (HOCs), and HUD's Management and Marketing (M&M) contractors to track single-family properties from their acquisition by HUD through the steps necessary to resell the properties. SAMS captures pertinent data relating to the properties, including acquisition, maintenance and sales cost, property description and value, bids and sales proceeds, and special program designations. Cases that have been in step 10, and subsequently without accounting activity for two years, are designated for archive and removed from SAMS. As a result of the

[1] *http://portal.hud.gov/hudportal/HUD?src=/program_offices/cio/privacy/pia/fednotice/SORNs_LoB*

archive process, all related case management and accounting data records are removed from the SAMS database. These case records do however, remain available in P260 and the Single Family Data Warehouse.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act other routine uses include:

(a) General Accounting Office (GAO) for audit purposes.

(b) Inspector General Office (IG) for audit purposes.

(c) IRS for tax purposes to allow payees to submit their 1099 miscellaneous form.

(d) Management and Marketing contractors for processing the sale of HUD Homes.

(e) Financial Control Contractors for processing for data input.

Additionally, refer to Appendix 1, HUD's Inventory of Routine Uses'' [2] section for a description of disclosures that may be applicable to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored electronically in a computer mainframe.

Asset Managers are required to keep closed case files for HUD properties sold for six months. After that, the AMs send the case files to storage. FHA is required to maintain all closed case files for properties for 40 years.

RETRIEVABILITY:

Records are retrieved by computer search by the FHA Case Number, Property Address, or Purchaser's name and/or social security number.

SAFEGUARDS:

Records are maintained in a secured computer network behind HUD's firewall. Access is limited to authorize personnel and requires a password and user ID before system access is granted.

RETENTION AND DISPOSAL:

Information is archived electronically and stored on magnetic tapes. Records will be retained and disposed of in accordance with the General Records Schedule included in HUD Handbook 2228.2, appendix 14, items 21–26. Paper base records are destroyed by burn or shredding. Electronic records are purged or deleted from the system when eligible to be destroyed using one of the methods described by the NIST SP 800–88 ''Guideline for media Sanitization'' (September 2006).

SYSTEM MANAGER AND ADDRESS:

TDB, Office of Single Family Asset Management, 451 Seventh Street SW., Room 9184, Washington, DC 20410.

RECORDS ACCESS AND NOTIFICATION PROCEDURES:

For information, assistance, or inquiry about the existence of records, contact the Privacy Act Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4178, Washington, DC 20410. (Attention: Capitol View Building, 4th Floor). Provide verification of your identity by providing two proofs of official identification. Your verification of identity must include your original signature and must be notarized. The Department's rules for providing access to records to the individual concerned appear in 24 CFR part 16.

CONTESTING RECORD PROCEDURES:

Procedures for the amendment or correction of records, and for applicants want to appeal initial agency determination appear in 24 CFR part 16. If additional information is needed, contact:

(i) In relation to contesting contents of records, the Privacy Act Officer at HUD, 451 Seventh Street SW., Room 4178 (Attention: Capitol View Building, 4th Floor), DC 20410;

(ii) In relation to appeals of initial denials, HUD, Departmental Privacy Appeals Officer, Office of General Counsel, 451 Seventh Street SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Purchasers, brokers, appraisers, contractors, and HUD employees.

EXEMPTIONS FROM CERTAIN PROVISIONS OF THE ACT:

None.

HSNG.SF/HWAA.02

SYSTEM NAME:

Single Family Insurance System—Claims Subsystem (A43C).

SYSTEM LOCATION:

The U.S. Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, and at the Single Family Insurance System—Claims Subsystem software is located on HUD's mainframe, which is located at 3200 Kanawha Turnpike. Building 6000, South Charleston, WV 25303. Backup facilities and infrastructure services are provided by SUNGUARD (184 Railroad Drive, Warminster, PA 18974) and Lockheed Martin (4701 Forbes Boulevard, Lanham, MD 20706) respectively.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

A43C maintains data on mortgagors that have obtained a HUD insured mortgage. The system also records the servicer and holder of HUD insured mortgages.

CATEGORIES OF RECORDS IN THE SYSTEM:

The Single Family Insurance System—Claims Subsystem includes mortgagor data such as FHA case number, mortgagor name, mortgagor Social Security Number, property address, and mortgage amount. Stored holder information includes the holder mortgagee name, holder number, holder address, and mortgagee reference number. Stored servicer information includes the servicer mortgagee name, servicer number, and servicer address.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

U.S. Housing Act of 1937 as amended (Pub. L. 75–412); National Housing Act of 1934; 24 CFR 203.35 (2013); 24 CFR 200.6 (2013); and 24 CFR 5.216 (2013).

DESCRIPTION AND SYSTEM PURPOSES:

The Single Family Insurance System—Claims Subsystem (CLAIMS) processes single family (SF) insurance claims against defaulted loans. CLAIMS also processes accounts receivables relating to SF claims, performs collection activities, processes cash receipts, and records accounts receivable activities as well as providing accounting information to users. The claims process is initiated when a servicing mortgagee completes and submits an application for Single Family Insurance Benefits (HUD Form 27011) to HUD headquarters, via Electronic Data Interchange (EDI), the FHA Connection, or paper. Each type of claim requires the submission of a Part A (Initial Application) and Part B (Fiscal Data). When submitting a paper conveyance claim, a Title Approval Letter (TAL) must accompany the claim. However, when transmitting the claim through EDI, the TAL is not submitted with the conveyance claim because the title approval data from A80S-Single Family Acquired Asset Management System (SAMS) is stored in an authorization file. Collection of a borrower's PII isn't required for performance of A43C's objective per say. A43C is a subset of A43 which is the system of record for insured single family loans. Prior to payment of claim for an insured loan through A43C, the loan needs to first be issued and insured

[2] *http://portal.hud.gov/hudportal/documents/huddoc?id=append1.pdf*

through A43. And in the process of the borrower obtaining an FHA-insured loan, their PII is required to be collected.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552 a(b) of the Privacy Act, other routine uses are as follows:

1. U.S. Treasury: A43C provides the Electronic Funds Transfer disbursement information to Treasury for claim payments.

2. eBits: Automated mailing contractor—Advice of Payment, (AOP), Billing, and Title Approval letters.

3. Federal Housing Administration (FHA)-Approved Lenders: Lenders submit claims using the Single Family Application for Insurance Benefits (Form HUD–27011) via Electronic Data Interchange (EDI), the FHA Connection, or paper. Form HUD–27011 includes PII such as name, Social Security Number, and property address. Upon analysis of the claim, the lender will receive from HUD TS824, ''Request for Correction'', stating any deficiencies that need to be corrected, or TS820, AOP, informing the lender that the claim has been paid.

4. SFIS (A43): The purpose of the outgoing interface to SFIS is to update the FHA insurance status to ''CLAIM'' and to provide an effective date for the status change upon authorization of a claim for payment.

5. CAIVRS (F57): Outgoing—With authorized lenders and Federal agencies for the purpose of prescreening applicants for loans or loans guaranteed by the Federal Government for the purpose of evaluating a loan applicant's creditworthiness. Provision of the Social Security Numbers of mortgagors associated with the initial claim payment (Part A) over the past three years.

6. FHASL (PO13): FHASL is provided with paid claims fiscal data from SFIS–CS and Loss Mitigation on a daily and monthly basis.

7. SFHEDW (D64A): SFIS–CS data is extracted and uploaded to the SFHEDW for analysis on a weekly basis.

8. CHUMS (F17): SFIS–CS receives indemnification information related to specific cases from CHUMS on a daily basis.

9. SAMS (A80S): Outgoing—Provides financial information for paid Conveyance claims or paid Supplemental claims with an original paid Conveyance claim on a daily basis. Additionally, the SAMS extract file (from ARS) provides case-level information for established and adjusted receivables on a monthly basis. Incoming—Defines whether Title Evidence was approved; title approval is a pre-requisite for processing Part B Conveyance claims.

10. SFMNS/IFS (A80N): Provides the Strategy Group with paid Loss Mitigation—Partial Claims (Claim Type 33) data daily for the monitoring of these Secretary-held subordinate notes.

11. FHAC (F17C): Outgoing—Provides lenders and HUD users with case status information and title approval via the Internet. Incoming—Provides the capability for authorized lender employees to submit individual claims for specified claim types.

12. IMF (F51): SFICS accesses the IMF to obtain lender institution information for the purpose of EFT payment and address generation.

13. EDIS (U26A): Transfer of the TS 998 to confirm receipt of a claim transmitted via Electronic Data Interchange. Transfer of the TS 820 and TS824 files to the respective trading partners for the servicer or holder to indicate either payment or suspension of incoming claims received as TS260 transactions. The TS824 transactions are error records from the A43C batch load process.

14. GNMA: Provides GNMA with paid claims information for FHA-insured loans in GNMA pools.

15. Fannie Mae: Fannie Mae, as a holder, receives data regarding paid claims information for FHA-insured loans through an Advice of Payment.

Additionally, refer to Appendix 1, HUD's Inventory of Routine Uses'' [3] section for a description of disclosures that may be applicable to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Various types of storage media are used depending on the method used for filing a claim. Paper claims are filed at our contractor's office after processing, while disks and tapes are used to store electronic records in multiple computer record systems. Computer Center: 2020 Union Carbide Drive, South Charleston, WV 25303.

RETRIEVABILITY:

Data regarding a claim filed on a HUD insured property is obtained using the FHA Case Number, property address, mortgagor's name, mortgagee servicing number, or mortgagee holder number. Data retrieval can be performed in several ways: Standard reports, access via online pre-programmed CICS screens in A43C, access via the FHA Connection for case information, and the Data Warehouse (D64A).

SAFEGUARDS:

Safeguards that are in place include: Lockable file cabinets; Secured computer facilities at HUD and their contractor's offices; Background checks of all HUD employees and contractor staff; Computer access to the multiple HUD record systems is restricted by passwords, defined individual access profiles (least privileges), and access to specified data fields is restricted. Users, whether at HUD Headquarters or the Homeownership Centers, obtain access to CLAIMS through a HUD INET communication link from their LAN to the IBM mainframe computer; Data is transmitted over secure T–1 and Shiva lines; Information about conveyed properties is available to the public via the Internet for marketing purposes. However, information covered by the Privacy Act of 1974 and the Right to Financial Privacy Act (12 U.S.C. 3401 et seq.) is not incorporated in any Internet site.

RETENTION AND DISPOSAL:

Obsolete data/backup tapes and/or hard drives are degaussed per DoD standards prior to disposal, release out of organizational control, or release for reuse. Further, tapes and hard drives are physically destroyed through shredding per DoD standards. However, defective/failed EMC SAND drives aren't degaussed or destroyed. Data is stored in a SAN and HPES uses a government-approved data wipe software. HPES then physically destroys the disk.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Single Family Post Insurance Division and Chief, Single Family Claims Branch; HUD, 451 Seventh Street SW., Room 6248, Washington, DC 20410.

NOTIFICATION AND RECORDS ACCESS PROCEDURES:

The Department's rules for providing access to records to the individual concerned are in accordance with 24 CFR part 16—Implementation of the Privacy Act of 1974. Individuals seeking information, assistance, or inquiry about the existence of records can contact the Departmental Privacy Act Officer at the Department of Housing and Urban Development, 451 Seventh Street SW., Room 4156, Washington, DC 20410. Written requests must include the full name, current address, and telephone number of the individual making the request, as well as proof of identity, including a description of the

[3] *http://portal.hud.gov/hudportal/documents/huddoc?id=append1.pdf*

requester's relation to the information in question.

RECORD ACCESS PROCEDURES:

The Department's rules for providing access to an individual's records appear in 24 CFR Part 16—Implementation of the Privacy Act of 1974. If additional information or assistance is required, contact the Departmental Privacy Act Officer.

CONTESTING RECORD PROCEDURES:

The procedures for requesting amendment or correction of records appear in 24 CFR part 16. If additional information is needed, contact:

(i.) In relation to contesting contents of records, the Privacy Act Officer at HUD, 451 Seventh Street SW., Room 4178 (Attention: Capitol View Building, 4th Floor), (202) 402–8073, Washington, DC 20410;

(ii.) In relation to appeals of initial denials, HUD, Departmental Privacy Appeals Officer, Office of General Counsel, 451 Seventh Street SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Record source categories include HUD/FHA Claims for Insurance Benefits, subject individuals; other individuals; credit bureaus; financial institutions; other corporations or firms; federal government agencies; non-federal (including foreign, state and local) government agencies; real estate brokers and agents.

EXEMPTIONS FROM CERTAIN PROVISIONS OF THE ACT:

None.

HSNG.SF/HUF.01

SYSTEM NAME:

Asset Disposition and Management System (ADAMS–VBSP–P260).

SYSTEM LOCATION:

SunGard, 1001 E Campbell Road, Richardson, TX 75081; SunGard, 120 Van Buren Street, Suite 202, Phoenix, AZ 85004 (Disaster Recovery site) Federal Records Center (at retirement), and at the HUD Headquarters building, 451 Seventh Street SW., Washington, DC 20410.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are covered by this system include successful bidders of a HUD-owned property, non-profit organizations, Government Entities, Nonprofit board members and key staff and Asset Control Area (ACA) participants approved by HUD to purchase HUD/FHA single-family homes. Also, individuals involved in the sale of HUD/FHA single-family homes Management and Marketing contractors (M&M), HUD employees, brokers, Name and Address identifier contractors, and financial control contractors.

CATEGORIES OF RECORD IN THE SYSTEM:

Files contain identifying information about successful bidders, such as name, Social Security Number, and current address. In addition, the files contain appraisal information, tax payments, purchase sales offer information, HUD–1, purchase contract information, vendor information, and Management and Marketing contractor invoice information. Additional Nonprofit/Government entity Business Documentation: (IRS Letters for Determination of Nonprofit Status, Articles of Organization; Mortgage Notes, W–9/SAMS–1111), Property Report Documentation (Median Income certification) and limited information about the homebuyers; such as, their name, and address, SSN, and race/ethnicity characteristics.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Housing Act as amended (12 U.S.C. 1702 et seq.). Housing and Urban Development 24 CFR 200.194 (Part 200— Introduction to FHA Programs)—Placement of Nonprofit Organization on Nonprofit Organization Roster. 42 U.S.C. 3543—Sec. 3543 Preventing fraud and abuse in Department of Housing and Urban Development programs, National Housing Act, Section 235(b), Public Law 479, 48 Stat. 12 U.S.C. 1701 et seq., Section 165 (a) of the Housing and Community Development Act of 1987, Public Law 100–242, Section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988, Public Law 100–628.

Purpose: ADAMS/P260 is a case management system for HUD owned and HUD managed single-family properties. The P260 application was introduced into production in 2010. ADAMS/P260 supports HUD staff at Headquarters and Homeownership Centers (HOCs), and HUD's Management and Marketing (M&M) contractors to track single-family properties from their acquisition by HUD through the steps necessary to resell the properties. ADAMS/P260 captures pertinent data relating to the properties, including acquisition, maintenance and sales cost, property description and value, bids and sales proceeds, and special program designations. ADAMS/P260 also tracks and monitors certain events after sales under the Good Neighbor Next Door, non-profit, and ACA sales programs. Additional Nonprofit/Government entity web-based program management tools improve the application, recertification, and reporting process for organizations that participate in the Office of Single Family Housing (OSFH) activities and to assist HUD staff with the daily administration of FHA's Nonprofit Program activities. HUD maintains a roster of nonprofit organizations that are qualified to participate in certain specified FHA activities. The Nonprofit data used by HUD staff to: (1) Verify an agency's eligibility to participate in the program; (2) to validate that no conflicts of interest exists amongst board members, employees, business partners, and homebuyers; (3) to validate that discounted HUD–REO homes were sold to eligible buyers; and (4) to determine that participating agencies have not exceeded profit limits on the re-sale of HUD–REO homes purchased through the discount program. However, because Government entities do not need approval to participate in the program they are not required to submit any business documentation or documentation on any governing boards or key staff. Government entities are required to submit property reports documenting the purchase and sell of REO discount properties.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act other routine uses include:

(a) General Accounting Office (GAO) for audit purposes.

(b) IRS for tax reporting purposes.

(c) Management and Marketing contractors for processing sales of HUD Homes as authorized by 24 CFR Part 291.

Additionally, refer to Appendix 1, HUD's Inventory of Routine Uses'' [4] section for a description of disclosures that may be applicable to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored electronically in a computer mainframe. No manual/paper based records.

RETRIEVABILITY:

Records are searched by FHA case number, property address (including other geographical characteristics such

[4] *http://portal.hud.gov/hudportal/documents/huddoc?id=append1.pdf.*

as contract area, property state/city/county/zip code, HUD Homeownership Center), contractor ID/name, or nonprofit/government agency name. No paper based records.

SAFEGUARDS:

Records are maintained in a secured computer network. Access is limited to authorized personnel. ADAMS (P260) access requires two levels of logins to access the system. The first login uses HUD Siteminder system to verify that the user has active HUD authorization. The second login uses ADAMS (P260) internal security system to set permissions for data access and system functionality. No paper based records.

RETENTION AND DISPOSAL:

Information is archived electronically. Records will be retained and disposed of in accordance with the General Records Schedule included in HUD Handbook 2228.2, appendix 14, items 21–26. At system retirement, records may be retained at the Federal Records Center. Paper base records are destroyed by burn or shredding. Electronic records are purged or deleted from the system when eligible to be destroyed using one of the methods described by the NIST SP 800–88 ''Guideline for media Sanitization'' (September 2006).

SYSTEM MANAGER AND ADDRESS:

Shawn Walkey, Office of Single Family Asset Management, 451 Seventh Street SW., Room 9182, Washington, DC 20410.

NOTIFICATION AND RECORD ACCESS PROCEDURES:

For information, assistance, or inquiry about the existence of records, contact the Privacy Act Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4178, Washington, DC 20410. (Attention: Capitol View Building, 4th Floor). Provide verification of your identity by providing two proofs of official identification. Your verification of identity must include your original signature and must be notarized. The Department's rules for providing access to records to the individual concerned appear in 24 CFR part 16.

CONTESTING RECORD PROCEDURES:

The procedures for requesting amendment or correction of records appear in 24 CFR part 16. If additional information is needed, contact:

(iii.) In relation to contesting contents of records, the Privacy Act Officer at HUD, 451 Seventh Street SW., Room 4178 (Attention: Capitol View Building, 4th Floor), (202) 402–8073, Washington, DC 20410;

(iv.) In relation to appeals of initial denials, HUD, Departmental Privacy Appeals Officer, Office of General Counsel, 451 Seventh Street SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Purchasers, Brokers, appraisers, contractors, Nonprofit/Government entities, and HUD employees.

EXEMPTIONS FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2014–04203 Filed 2–25–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2013–N214; 80221–1113–0000–C2]

Endangered and Threatened Wildlife and Plants; Final Recovery Plan for Tidal Marsh Ecosystems of Northern and Central California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of the final recovery plan for three endangered plants, *Cirsium hydrophilum* var. *hydrophilum* (Suisun thistle), *Chloropyron molle* ssp. *molle* (soft bird's-beak), and *Suaeda californica* (California sea-blite), and two endangered animals, California clapper rail (*Rallus longirostris obsoletus*) and salt marsh harvest mouse (*Reithrodontomys raviventris*). The recovery plan includes recovery objectives and criteria, and specific actions necessary to achieve downlisting and delisting from the Federal Lists of Endangered and Threatened Wildlife and Plants.

ADDRESSES: You may obtain a copy of the recovery plan from our Web site at *http://www.fws.gov/endangered/species/recovery-plans.html.* Alternatively, you may contact the Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, Suite W–2605, Sacramento, CA 95825 (telephone 916–414–6700).

FOR FURTHER INFORMATION CONTACT: Jennifer Norris, Field Supervisor, at the above street address or telephone number (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION:

Background

Recovery of endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of our endangered species program and the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). Recovery means improvement of the status of listed species to the point at which listing is no longer appropriate under the criteria specified in section 4(a)(1) of the Act. The Act requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species.

The three plants, *Cirsium hydrophilum* var. *hydrophilum, Chloropyron molle* ssp. *molle,* and *Suaeda californica,* along with both animals, California clapper rail and salt marsh harvest mouse, inhabit tidal marsh ecosystems in central California. We listed *C. hydrophilum* var. *hydrophilum* and *C. molle* ssp. *molle* on November 20, 1997 (62 FR 61916), and *S. californica* on December 15, 1994 (59 FR 64613). *C. molle* ssp. *molle* is the currently accepted scientific name for this species, although the species was originally listed under the scientific name *Cordylanthus mollis* ssp. *mollis* and remains listed that way in the List of Endangered and Threatened Plants at 50 CFR 17.12(h). However, we will soon issue a proposed rule to update the taxonomy for this species on the List of Endangered and Threatened Plants, so throughout the rest of this document we refer to this species with the scientific name *C. molle* ssp. *molle.*

We listed the California clapper rail and salt marsh harvest mouse on October 13, 1970 (35 FR 16047). A recovery plan for the California clapper rail and salt marsh harvest mouse was published on November 16, 1984 (USFWS 1984, pp. 1–141). However, since a substantial amount of additional information is now available, it is appropriate to revise the plan to incorporate this new information, and to add the more recently listed plant species into the recovery program. Further, the plan has been expanded to include a comprehensive restoration and management component of the tidal marsh ecosystems of the area.

In addition to the five entities above, the Tidal Marsh Ecosystems of Northern and Central California recovery plan includes information related to *Chloropyron maritimum* ssp. *maritimum* (salt marsh bird's-beak), which we listed as endangered on September 28, 1978 (43 FR 44810). *C. maritimum* ssp. *maritimum* is the

currently accepted scientific name for this species, although the species was originally listed under the scientific name *Cordylanthus maritimus* ssp. *maritimus* and remains listed that way in the List of Endangered and Threatened Plants at 50 CFR 17.12(h). However, we will soon issue a proposed rule to update the taxonomy for this species on the List of Endangered and Threatened Plants, so throughout the rest of this document we refer to this species with the scientific name *C. maritimum* ssp. *maritimum.* The northern range limit of *C. maritimum* ssp. *maritimum* is in Morro Bay; however, Morro Bay was omitted from the Salt Marsh Bird's-Beak Recovery Plan (U.S. Fish and Wildlife Service 1985*a*) because the taxonomic interpretation at the time classified this population in another subspecies that is not federally listed. Current taxonomic interpretation considers the Morro Bay population as *C. maritimum* ssp. *maritimum.* Therefore, we include recovery goals for this northern population.

Section 4(f) of the Act requires us to provide an opportunity for public review and comment prior to finalization of recovery plans, including revisions to such plans. We made the draft of this revised recovery plan available for public comment from February 10, 2010 to June 10, 2010 (75 FR 6696). We considered all information we received during the public comment period and revised the recovery plan accordingly.

Species Information

Cirsium hydrophilum var. hydrophilum

Cirsium hydrophilum var. *hydrophilum* was once widespread in Suisun Marsh, but, due to habitat loss, in the last two decades has been found in only four localities: Grizzly Island, Peytonia Slough, Rush Ranch, and Hill Slough. These populations have been in decline since the 1990s and 2000s.

Chloropyron molle ssp. molle

Chloropyron molle ssp. *molle,* though threatened by past habitat loss, retains populations in the tidal marshes of Napa-Sonoma, Point Pinole, Carquinez Straits, Suisun Marsh area, and northern Contra Costa County. These populations are composed of many shifting colonies or subpopulations, with great variability in population size and distribution.

Suaeda californica

Suaeda californica occurred historically in high tidal marsh in portions of San Francisco Bay, where it became nearly extinct because of habitat loss. Due to several reintroductions between 1999 and 2008, it is currently known from three sites in the San Francisco Bay and scattered locations along the shoreline of Morro Bay, San Luis Obispo County.

California Clapper Rail

The historic range of California clapper rails may have extended from tidal marshes of Humboldt Bay to Morro Bay; however, the species now occurs only within the tidal and brackish marshes around San Francisco Bay where it is restricted to less than 10 percent of its former geographic range. Population numbers reached an all-time historical low of about 500 birds in 1991, then rebounded somewhat. Results of an estuary-wide survey estimated a minimum average population between 2005 and 2008 of 1,425 rails (Liu *et al.* 2009); however, population numbers declined during that period at a per-year rate of 20 percent, as habitat was lost bay-wide, and are currently lower.

Salt Marsh Harvest Mouse

The two subspecies of salt marsh harvest mouse are restricted to the tidal and brackish marshes of San Francisco Bay, San Pablo Bay, and Suisun Bay areas. The southern subspecies inhabits central and south San Francisco Bay, and has suffered severe habitat loss and fragmentation. Less than 10 percent of its historic habitat acreage remains, and nearly all is deficient in its structural suitability. The northern subspecies, living in the marshes of San Pablo and Suisun bays, has also sustained extensive habitat loss and degradation, but less so than the southern subspecies.

These species occur in a variety of tidal marsh habitats where they are limited by the requirements of moisture, salinity, topography, soil types, and climatic conditions. Adjacent uplands and ecotone areas are also crucial habitats for many of these species. Primary threats to all the listed species include historical and current habitat loss and fragmentation due to urban development, agriculture, and diking related to duck hunting; altered hydrology and salinity; nonnative invasive species; disturbance; contamination; risk of extinction due to small population size; and the most central threat, sea level rise due to climate change.

Recovery Plan Goals

The purpose of a recovery plan is to provide a framework for the recovery of species so that protection under the Act is no longer necessary. A recovery plan includes scientific information about the species and provides criteria that enable us to gauge whether downlisting or delisting the species is warranted. Furthermore, recovery plans help guide our recovery efforts by describing actions we consider necessary for each species' conservation and by estimating time and costs for implementing needed recovery measures.

The ultimate goal of this recovery plan is to recover all focal listed species so that they can be delisted. The interim goal is to improve the status of the focal listed species to the point that they can be reclassified from endangered to threatened status. For *Chloropyron maritimum* ssp. *maritimum,* the goal is to support recovery as described in the Salt Marsh Bird's-Beak Recovery Plan (U.S. Fish and Wildlife Service 1985*a*).

The recovery plan contains the following five ecosystem-level strategies for recovery, which we believe will promote a healthy, stable ecosystem for populations of these species:

1. Acquire existing, historic, and restorable tidal marsh habitat to promote the recovery of listed species and the long-term conservation of species of concern and other tidal marsh species;
2. Manage, restore, and monitor tidal marsh habitat to promote the recovery of listed species and the long-term conservation of species of concern and other tidal marsh species;
3. Conduct rangewide species status surveys/monitoring and status reviews for listed species and species of concern;
4. Conduct research necessary for the recovery of listed species and the long-term conservation of species of concern; and
5. Improve coordination, participation, and outreach activities to achieve recovery of listed species and long-term conservation of species of concern.

As these species meet reclassification and recovery criteria, we will review each species' status and consider each species for reclassification or removal from the Federal Lists of Endangered and Threatened Wildlife and Plants.

Authority

We developed our recovery plan under the authority of section 4(f) of the Act, 16 U.S.C. 1533(f). We publish this notice under section 4(f) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: February 20, 2014.

Alexandra Pitts,

Regional Director, Pacific Southwest Region.

[FR Doc. 2014–04138 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14200000–BK0000]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on March 28, 2014.

DATES: Protests of the survey must be filed before March 28, 2014 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Thomas Trzinski, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5364 or (406) 896–5009, *ttrzinsk@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the BLM, Miles City Field Office, and was necessary to determine federal interest lands. The lands we surveyed are:

Principal Meridian, Montana

T. 1/2 N., R. 40 E.

The plat, in two sheets, representing the dependent resurvey and survey of Township 1/2 North, Range 40 East, Principal Meridian, Montana, was accepted February 7, 2014.

We will place a copy of the plat, in two sheets, we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in two sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in two sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Josh Alexander,

Acting Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2014–04141 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNML00000.L71220000.EU0000 LVTFG11G4360; NMNM 125550]

Notice of Realty Action: Non-Competitive (Direct) Sale of Public Land in Otero County, NM

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) will offer to sell a parcel of public land totaling 10 acres in Otero County, New Mexico. The BLM will consider a direct sale to Todd Taylor, the adjoining landowner, under the provisions of the Federal Land Policy and Management Act of 1976 (FLPMA), to resolve an inadvertent occupancy trespass. The BLM will not sell the parcel for less than the appraised fair market value of $49,000.

DATES: Interested parties may submit written comments regarding the proposed sale and received by the BLM on or before April 14, 2014.

ADDRESSES: You may submit written comments regarding the proposed sale by any of the following methods:

- *Email: blm_nm_lcdo_comments@blm.gov.*
- *Fax:* 575–525–4412, Attention: Frances Martinez.
- *Mail or personal delivery:* Frances Martinez, Taylor Land Sale Project Lead, BLM Las Cruces District Office, 1800 Marquess Street, Las Cruces, New Mexico 88005.

Comments expressed verbally will not be accepted.

FOR FURTHER INFORMATION CONTACT: Frances Martinez, Realty Specialist, at the address above, by telephone 575–525–4385, or by email at *fmartine@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM will consider the public land described below for direct sale in accordance with Section 203 of FLPMA (43 U.S.C. 1713).

New Mexico Principal Meridian

T. 13 S., R. 11 E.,
Sec. 28, NE¼NE¼NE¼.

The area described contains 10 acres in Otero County, New Mexico.

The BLM will consider selling the 10-acre parcel through a direct sale of public lands to resolve an inadvertent occupancy trespass. 43 CFR 2711.3–3(a)(5). The parcel proposed for sale is the smallest size possible to resolve the trespass. The BLM identified the parcel as suitable for disposal in the White Sands Resource Management Plan (RMP), dated October 1986, and the September 1986 Record of Decision. The sale meets the criteria for disposal in Section 203(a)(1), (d) and (f)) of FLPMA and regulations in 43 CFR 2710.0–3(a)(3) and 43 CFR 2711.3–3(a)(5). A residential house, domestic well, septic system, access road, and utilities constitute the inadvertent occupancy to be resolved by the proposed sale. The patent will contain a reservation to the United States of all minerals in accordance with regulation 43 CFR 2711.5.

The BLM must receive the purchase price paid by certified check, postal money order, bank draft or cashier's check payable to the BLM within 90 days of the sale. Failure to submit the proceeds for the land will constitute a waiver of this preference consideration. No representation, warranty or covenant of any kind, express or implied, will be given or made by the United States, its officers or employees, as to access to or from the above described parcel of land, the title to the land, whether or to what extent the land may be developed, its physical condition or its past, present or potential uses, and the conveyance of any such parcel will not be on a contingency basis. The purchaser must be responsible for and aware of all applicable Federal, State, and local government policies and regulations that would affect the subject land. It is also the purchaser's responsibility to be aware of existing or prospective uses of nearby properties. Any land lacking access from a public road or highway will be conveyed as such, and future access acquisition will be the responsibility of the purchaser. To the extent required by law, the sale will be subject to the requirements of Section 120(h) of the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C 9620(h)).

As proposed, the sale will be made, and the land will be conveyed, reserving to the United States:

1. A right-of-way thereon for ditches and canals reserved by the United States pursuant to the Act of August 30, 1890 (43 U.S.C. 945);

2. All the mineral deposits in the lands so patented, and the right of the United States or persons authorized by the United States to prospect for, mine and remove such deposits from the same under applicable laws and regulations as the Secretary of the Interior may prescribe.

The BLM will convey the lands subject to:

1. Valid existing rights;

2. Local zoning and subdivision laws, if any;

3. Right-of-way NMNM 13513 for Federal aid highway purposes granted to the New Mexico State Highway Department, its successors or assigns, pursuant to the Act of August 27, 1958, (23 U.S.C. 317).

By accepting deed/patent, and to the extent allowed by law, the purchaser agrees to indemnify, defend and hold harmless the United States from any cost, damages, claims, causes of action, penalties, fines, liabilities, and judgments of any kind or nature arising from past, present, and future acts or omissions of the purchaser, its employees, agents, contractor, or lessees, previous landowners or subsequent landowners or contractors, or lessees, or any third party, arising out of, or in connection with, the purchaser's use, occupancy, or operations on the real property which has already resulted or does hereafter result in: (1) Violations of Federal, State, and local laws and regulations which are now or may in the future become applicable to the real property; (2) Judgments, claims and demands of any kind assessed against the United States; (3) Cost, expense or damages of any kind incurred by the United States; (4) Releases or threatened releases of solid or hazardous waste(s) and/or hazardous substance(s), pollutant(s) or containment(s), and/or petroleum product or derivative of a petroleum product, as defined by Federal and State environmental laws, off, on, into, or under land, property, and other interests of the United States; (5) Other activities by which solid or hazardous substances or wastes, as defined by Federal and State environmental laws, were generated, released, stored, used, or otherwise disposed of on the real property, and any cleanup, response or remedial action, or other actions related in any manner to said solid or hazardous substance(s) or waste(s); or (6) Natural resource damages as defined by Federal and State law.

This covenant shall be construed as running with the real property, and may be enforced by the United States in a court of competent jurisdiction.

All persons claiming to own unauthorized improvements on the land are allowed 60 days from the date of sale to remove the improvements.

On February 26, 2014, the above described land will be segregated from all forms of appropriation under the public land laws, including the general mining laws, except the sale provisions of FLPMA. Until completion of the sale, the BLM is no longer accepting land use applications affecting the identified public land, except applications for the amendment of previously filed right-of-way applications or existing authorizations to increase the term of the grants in accordance with 43 CFR 2807.15 and 2886.15. The segregation will terminate upon issuance of a patent, publication in the **Federal Register** of a termination of the segregation, or February 26, 2016, whichever occurs first, unless extended by the BLM State Director, in accordance with 43 CFR 2711.1–2(d) prior to the termination date.

The public land will not be offered for sale until April 28, 2014.

On or before April 14, 2014, any person may submit written comments regarding the proposed sale directly to the BLM using one of the methods listed in the **ADDRESSES** section above.

Comments, including names, street addresses, and other contact information of respondents, will be available for public review. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, are available for public inspection in their entirety.

Detailed information, including the appraisal, the Environmental Assessment and the Decision relative to this direct land sale is available at the BLM Las Cruces District Office, 1800 Marquess Street, Las Cruces, New Mexico, during regular business hours between 7:45 a.m. to 4:30 p.m. The BLM Las Cruces District Manager will review objections and may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

(Authority: 43 CFR 2711.1–2)

Michael H. Tupper,

Deputy State Director, Lands and Resources.

[FR Doc. 2014–04178 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–BSD–FEES–14548; PX.XBSAD0096.00.1]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; The Interagency Access Pass and Senior Pass Application Processes

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on February 28, 2014. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before March 28, 2014.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Information Collection Clearance Officer, National Park Service, 1849 C Street NW. (2601), Washington, DC 20240 (mail); or *madonna_baucum@nps.gov* (email). Please reference OMB Control Number 1024–0252 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Brooke Linford by email at *brooke_linford@nps.gov*, or at 202–513–7139 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the

Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

I. Abstract. The America the Beautiful—National Parks and Federal Recreation Lands Pass Program covers recreation opportunities on public lands managed by four Department of the Interior agencies—the National Park Service, U.S. Fish and Wildlife Service, Bureau of Land Management, and the Bureau of Reclamation—and by the Department of Agriculture's U.S. Forest Service. The passes provide visitors an affordable and convenient way to access Federal recreation lands. The pass program's proceeds are used to improve and enhance visitor recreation services. Two of the available passes—Interagency Access Pass and Interagency Senior Pass—require documentation and are the bases for this information collection.

The Interagency Access Pass is a free, lifetime pass issued to citizens or residents who are domiciled in the United States, regardless of age, and who have a medical determination and documentation of permanent disability. You can obtain an Access Pass in person, with proper documentation, from a participating Federal recreation site or office. Access Passes may also be obtained via mail order. Mail-order applicants for the Access Pass must submit a completed application, proof of residency, and documentation of permanent disability, and pay the document processing fee of $10 to obtain a pass through the mail.

If a person arrives at a recreation site and claims eligibility for the Interagency Access Pass, but cannot produce any documentation, that person must read, sign, and date a Statement of Disability Form in the presence of the agency officer issuing the Interagency Access Pass. If the applicant cannot read and/or sign the form, someone else may read, date, and sign the statement on his/her behalf in the applicant's presence and in the presence of the agency officer issuing the Interagency Access Pass.

The Interagency Senior Pass is a lifetime pass issued to U.S. citizens or permanent residents who are 62 years or older. There is a $10 fee for the Senior Pass. You can buy a Senior Pass in person from a participating Federal recreation site or office or by mail order. There is an additional document processing fee of $10 to obtain a Senior Pass through the mail. Mail-order applicants must submit a completed application and proof of residency and age, and pay $20 for the pass fee and processing fee.

Agency Web sites provide information on the passes and acceptable documentation. All documentation submitted in person or through the mail is returned to the applicant or destroyed.

II. Data

OMB Control Number: 1024–0252.

Title: The Interagency Access Pass and Senior Pass Application Processes.

Service Form Number(s): None.

Type of Request: Revision of a currently approved collection.

Description of Respondents: Individuals.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity	Number of respondents	Number of annual responses	Completion time per response (minutes)	Total annual burden hours
Interagency Access Pass (in person)	76,000	76,000	5	6,333
Interagency Access Pass (by mail)	4,000	4,000	10	667
Interagency Senior Pass (by mail)	29,750	29,750	10	4,958
Totals	109,750	109,750	.....	11,958

Estimated Annual Nonhour Burden Cost: $359,775 ($337,500 for processing fees and $22,275 for copying and postage costs).

III. Comments

On October 22, 2013, we published in the **Federal Register** (78 FR 62657) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on December 23, 2013. We did not receive any comments.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: February 20, 2014.

Doris Lowery,

Acting, Information Collection Clearance Officer, National Park Service.

[FR Doc. 2014–04058 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–EH–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–VRP–WS–15009; PPWOVPADW0, PPMPRLE1Y.LB0000]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Backcountry Use Permit

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on February 28, 2014. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this

information collection while it is pending at OMB.

DATES: You must submit comments on or before March 28, 2014.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB—OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to Madonna L. Baucum, Information Collection Clearance Officer, National Park Service, 1849 C Street NW. (2601), Washington, DC 20240 (mail); or *madonna_baucum@nps.gov* (email). Please include ''1024–0022'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Robert Danno at *Robert_Danno@nps.gov* (email) or at 406–647–7010 (telephone). You may review the ICR online at *http://www.reginfo.gov*. Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1024–0022.

Title: Backcountry Use Permit, 36 CFR 1.5, 1.6, and 2.10.

Service Form Number(s): 10–404A.

Type of Request: Revision of a currently approved collection.

Description of Respondents: Individuals.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity	Number of respondents	Number of annual responses	Completion time per response (minutes)	Total annual burden hours
Form 10–404A	285,000	285,000	5	23,750
Totals	285,000	285,000	5	23,750

Estimated Annual Nonhour Burden Cost: None.

Abstract: In 1976, we initiated a backcountry registration system in accordance with the regulations found at Title 36, Code of Federal Regulations, Sections 1.5, 1.6, and 2.10. The backcountry use permit system provides users access to backcountry areas of national parks with continuing opportunities for solitude, while enhancing resource protection and providing a means of disseminating public safety messages regarding backcountry travel.

The Backcountry Use Permit is an extension of our statutory authority and responsibility to protect the park areas we administer and to manage the public use thereof (Title 16 United States Code, Sections 1 and 3 (16 U.S.C. 1 and 3)). NPS regulations codified in 36 CFR 1–7, 12, and 13, are designated to implement statutory mandates that provide for resource protection and public enjoyment.

The Backcountry Use Permit (NPS Form 10–404A) is the primary form used to implement a backcountry reservation system and provide access into backcountry and designated wilderness areas where registration is required or limits are imposed in accordance with regulations. Such permitting enhances the ability of the National Park Service (we, NPS) to issue hazard warnings, conduct search and rescue efforts, and provide mission based resource protection.

The objectives of the permit system are to ensure: (1) requests by backcountry users are evaluated by park managers in accordance with applicable statutes and NPS regulations; (2) use of consistent standards and permitting criteria throughout the agency; and (3) to the extent possible, use of a single and efficient permitting document.

Forms will be provided by the parks and will be available at backcountry reservation offices in the parks. Respondents complete the form as they reach the trailhead or backcountry reservation office and before beginning their backcountry hike. A copy is retained by the respondent, and a copy is retained by the park. Backcountry users only need to fill the form out when they enter the backcountry for overnight stays. Day users will not be required to complete the form.

Not all parks will use the form and some parks may collect the information using a nonform format (through discussions in person or over the phone, by sign-in sheet or self-registration system, by email, or by post card). In some instances, respondents will be able to provide information verbally. Because of the span of activities and the different management needs and resources at each park, respondents may not be required to answer all questions. Depending on the requested activity, park staff will have the discretion to ask for less information than appears on the proposed form. However, park staff may not ask for more or different information.

Comments: On April 2, 2013, we published in the **Federal Register** (78 FR 19732) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending June 3, 2013.

We received one comment. The comment was confined to issues at Grand Canyon National Park, specifically the aircraft overflight issue. The commenter suggested that NPS require backcountry permits be issued to individuals who participate in private scenic air tours over park lands. These excursions are short-term (1 hour or less) flights that originate outside the park. Although the flights often take place over park lands, the NPS does not have authority over airspace, which is under the authority of the Federal Aviation Administration. We did not make any changes to our information collection requirements.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: February 21, 2014.

Doris Lowry,

Acting Information Collection Clearance Officer, National Park Service.

[FR Doc. 2014–04175 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–EH–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–PWRO–14407; PX.P0131800B.00.1]

Final Environmental Impact Statement for the Merced Wild and Scenic River Comprehensive Management Plan, Yosemite National Park, Madera and Mariposa Counties, California

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA), and consistent with the National Historic Preservation Act of 1966 (NHPA), the National Park Service (NPS) has prepared the Final Environmental Impact Statement (Final EIS) for the proposed Merced Wild and Scenic River Comprehensive Management Plan (Merced River Plan). The Merced River Plan fulfills the requirements of the Wild and Scenic Rivers Act (Pub. L. 100–149, as amended) and will provide long-term protection of river values and establish a user capacity management program for 81 miles of the Merced River that flow through Yosemite National Park and the El Portal Administrative Site.

DATES: The NPS will execute a Record of Decision not sooner than 30 days after the date the U.S. Environmental Protection Agency publishes its notice of filing of the Final EIS for the Merced River Plan in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Kathleen S. Morse, Planning Chief, Yosemite National Park, P.O. Box 577, Yosemite, CA 95389, (209) 379–1110. Printed documents (quantities limited) or CDs may be requested through email (*yose_planning@nps.gov*) or by telephone (209) 379–1110. In addition, the Final EIS will be available for public inspection at libraries in local communities. Electronic versions will be available at *http://parkplanning.nps.gov/yose_mrp,* as well as through the Yosemite National Park Web site at *http://www.nps.gov/yose/parkmgmt/mrp.htm.*

Background

As defined by the Wild and Scenic Rivers Act (WSRA), the purposes of the Merced River Plan/Final EIS are to protect the Merced River's free-flowing conditions, and to: (1) Review, and if necessary revise, the river corridor boundaries and segment classifications, and provide a process for protection of the river's free-flowing condition in keeping with § 7(a) of the WSRA; (2) Refine descriptions of the river's outstandingly remarkable values (ORVs), which are the unique, rare, or exemplary in a regional or national context, and the river-related/river-dependent characteristics that make the river eligible for inclusion in the national wild and scenic rivers system; (3) Identify management objectives for the river and specific management measures that will be implemented to achieve protection and enhancement of river values; (4) Establish a user capacity program that addresses the kinds and amounts of public use that the river corridor can sustain while protecting and enhancing the river's ORVs; (5) Commit to a program of ongoing studies and monitoring to ensure that the ORVs are protected and enhanced over the life of the plan.

The Merced River Plan/Final EIS has been developed through consultation with traditionally-associated American Indian tribes and groups, the State Historic Preservation Officer, U.S. Fish and Wildlife Service, and other federal and state agencies. Gateway communities, organizations, and interested members of the public have provided more than 30,000 public correspondences (including letters, faxes, emails, comment forms, and public meeting flip-chart notes). The NPS has conducted more than 50 public meetings, presentations, workshops, field visits, and open houses in support of the EIS process. Two preliminary alternatives concepts workbooks were distributed for public review and comment prior to completion of the draft Merced River Plan.

Based on a thorough examination of the river's baseline conditions at the time of designation (1986), a multi-faceted approach to river management and stewardship has been proposed. To address the WSRA mandate to protect and enhance river values, many of the plan's actions would be common to all the action alternatives, including: (1) All WSRA management elements (boundaries, classifications, § 7 determination process); (2) actions to protect and enhance river values (e.g., ecological restoration components); (3) removal and or relocation of numerous facilities and services; (4) actions to improve traffic circulation and reduce congestion; (5) implementation of a monitoring program that sets thresholds for when management actions must be taken to protect river values; and (6) a user capacity management program.

Proposal and Alternatives

In keeping with the expressed purpose and need for federal action, the Merced River Plan/Final EIS evaluates the foreseeable environmental consequences of five action alternatives and a No-Action alternative in accordance with the NEPA, and assesses the potential to cause adverse effects to historic properties in accordance with § 106 of the NHPA. Actions called for in the 1980 Yosemite General Management Plan addressing management within the river corridor would be amended and are outlined in the Merced River Plan/Final EIS. The action alternatives vary primarily in the degree of restoration and the amount of visitor use that could be accommodated by the commensurate level of facilities and services necessary to protect river values.

Alternative 1 (No-Action) would continue current management and trends, including ongoing localized effects associated with impacts to free-flowing condition of the river and connectivity of meadows, development near the river's edge and floodplain, and pedestrian-vehicle conflicts at major intersections. In 2011, the peak daily visitation recorded for East Yosemite Valley was 20,900 people per day.

Alternative 2: Self-Reliant Visitor Experiences and Extensive Floodplain Restoration provides for restoration within the 100-year floodplain, significant reduction in facilities and services, and significantly lower visitor use than current conditions. Given the conditions in this Alternative, visitation to East Yosemite Valley would be approximately 13,900 people per day.

Alternative 3: Dispersed Visitor Experiences and Extensive Riverbank Restoration provides for restoration within 150 feet of the river, marked reduction in visitor facilities and services, and significantly lower visitor use than current conditions. Given the conditions in this Alternative, East Yosemite Valley visitation would be approximately 13,200 people per day.

Alternative 4: Resource-based Visitor Experiences and Targeted Riverbank Restoration provides for targeted restoration within 150 feet of the river, reduced commercial services with a significant increase over current camping opportunities, and slightly lower visitor use levels. Given conditions in this Alternative, East Yosemite Valley visitation would be approximately 17,000 people per day.

Alternative 5 (agency-preferred and environmentally preferred): Enhanced Visitor Experiences and Essential

Riverbank Restoration provides for essential restoration within 100 feet of the river, moderately increases current camping opportunities, and accommodates approximately the current level of visitor use. Given the conditions in this Alternative, East Yosemite Valley visitation would be approximately 20,100 people per day. Changes incorporated in this alternative based on public review of the Draft EIS are summarized below.

Alternative 6: Diversified Visitor Experiences and Selective Riverbank Restoration provides for limited restoration within 100 feet of the river, expanded facilities and services with the largest increase over current camping opportunities, and accommodation of some growth in visitor use levels. Given conditions in this Alternative, East Yosemite Valley visitation would be approximately 21,800 people per day.

Changes Incorporated in Final EIS

In response to comments received on the Draft EIS, some modifications have been incorporated into Alternative 5 (key changes are listed below); all other alternatives are substantially unchanged.

- Revised the user capacity and visitor use management program to better articulate how river values, transportation system performance, and management objectives work together to develop and monitor user capacities.
- Increased the number of sites at the Upper and Lower River Campgrounds, and eliminated proposed camping at Eagle Creek. Added campsites to the Abbieville/Trailer Village area and increased the number of spaces at the seasonally-available El Portal Remote Parking Area.
- Retained the Ahwahnee and Yosemite Lodge pools, relocated bike rentals and ice skating facilities outside the river corridor, provided raft rental opportunities, and retained the Housekeeping Camp store.
- Allowed commercial raft rentals in Yosemite Valley and included a boating capacity and additional boating information for each open segment of river.
- Removed the proposed Huff House employee housing and redistributed these units with additional permanent housing at Lost Arrow, retained historic housing in the Curry Village area, and included new units in Rancheria Flat as well as the El Portal Town Center.
- Included additional tour bus parking at the West of Lodge parking area and additional parking spaces in areas such as east of the Yosemite Lodge registration area and the current Curry Village ice-rink location. Relocated parking from West Valley Overflow Parking Area to the El Portal Remote Parking area where shuttle service to Yosemite Valley would be provided. Established a commercial tour bus and transit capacity for Yosemite Valley.
- Further study will assess various long-term management strategies for Sugar Pine Bridge. If mitigation measures fail to meet defined criteria for success, consideration of bridge removal would involve a public review process and additional compliance.
- Clarified changes to Curry Village overnight accommodations to reflect recent changes due to the rockfall hazard zone update.
- A tiered compliance effort will evaluate alternatives to address a grade-separated pedestrian crossing to address traffic congestion at the Yosemite Lodge intersection.
- Expanded the Yosemite Valley Historic Resources ORV to include the entire Yosemite Valley Historic District and clarified specific sites where monitoring will occur to protect and enhance the Recreation ORV.
- Established a grazing capacity at Merced Lake East Meadow and pack stock limit for the Merced Lake High Sierra Camp.

Decision Process

As noted above, not sooner than 30 days after the Environmental Protection Agency notice is published in the **Federal Register**, the National Park Service will prepare a Record of Decision. Because this is a delegated EIS, the official responsible for approval of the Merced River Plan is the Regional Director, Pacific West Region, National Park Service. Subsequently, the official responsible for implementation of the approved Merced River Plan is the Superintendent, Yosemite National Park.

Dated: November 4, 2013.

Christine S. Lehnertz,

Regional Director, Pacific West Region.

[FR Doc. 2014–04061 Filed 2–25–14; 8:45 am]

BILLING CODE 4312–FF–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–BOHA–14837; PPMPSPD1Z.YM0000; PPNEBOHAS1]

Boston Harbor Islands National Recreation Area Advisory Council Annual Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces the annual meeting of the Boston Harbor Islands National Recreation Area Advisory Council.

DATES: The annual meeting of the Boston Harbor Islands National Recreation Area Advisory Council will be held March 5, 2014, 4:00 p.m. to 6:00 p.m. (EASTERN).

ADDRESSES: The meeting will be held at WilmerHale, 60 State Street, 26th floor, Boston, MA 02109.

FOR FURTHER INFORMATION CONTACT: Giles Parker, Superintendent and Designated Federal Officer (DFO), Boston Harbor Islands National Recreation Area, 15 State Street, Suite 1100, Boston, MA 02109, by telephone (617) 223–8669, or email *giles_parker@nps.gov.*

The agenda will include:

- Presentation on Youth Engagement in the Park
- 2016 Anniversaries Update
- Update on Work at the Chapel on Peddocks Island
- Election of Officers
- Park Updates

SUPPLEMENTARY INFORMATION: The Council was appointed by the Director of the National Park Service pursuant to Public Law 104–333. The purpose of the Council is to advise and make recommendations to the Boston Harbor Islands Partnership with respect to the implementation of a management plan and park operations. Efforts have been made locally to ensure that the interested public is aware of the meeting dates.

This meeting is open to the public. Those wishing to submit written comments may contact the DFO by mail at National Park Service, Boston Harbor Islands National Recreation Area, 15 State Street, Suite 1100, Boston, MA 02109, or via email: *giles_parker@nps.gov.* Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice is being published less than 15 days prior to the meeting due to the special emphasis of the meeting.

Dated: February 21, 2014.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2014–04179 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–WV–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0081]

Information Collection: Operations in the Outer Continental Shelf for Minerals Other Than Oil, Gas, and Sulphur; Proposed Collection for OMB Review; Comment Request; MMAA104000

ACTION: 60-day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Ocean Energy Management (BOEM) is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in the regulations under 30 CFR 582, Operations in the Outer Continental Shelf for Minerals Other than Oil, Gas, and Sulphur.

DATES: Submit written comments by April 28, 2014.

ADDRESSES: Please send your comments on this ICR to the BOEM Information Collection Clearance Officer, Arlene Bajusz, Bureau of Ocean Energy Management, 381 Elden Street, HM–3127, Herndon, Virginia 20170 (mail); or *arlene.bajusz@boem.gov* (email); or 703–787–1209 (fax). Please reference ICR 1010–0081 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Arlene Bajusz, Office of Policy, Regulations, and Analysis at (703) 787–1025 to request a copy of the ICR.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1010–0081.

Title: 30 CFR 582, Operations in the Outer Continental Shelf for Minerals Other than Oil, Gas, and Sulphur.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1334 and 43 U.S.C. 1337(k)), authorizes the Secretary of the Interior to implement regulations to grant to the qualified persons, offering the highest cash bonus on a basis of competitive bidding, leases of any mineral other than oil, gas, and sulphur. This applies to any area of the OCS not then under lease for such mineral. This regulation governs mining operations within the OCS for minerals other than oil, gas and sulphur and establishes a comprehensive leasing and regulatory program for such minerals. These regulations have been designed to (1) recognize the differences between the OCS activities associated with oil, gas, and sulphur discovery and development and those associated with the discovery and development of other minerals; (2) facilitate participation by States directly affected by OCS mining activities; (3) provide opportunities for consultation and coordination with other OCS users and uses; (4) balance development with environmental protection; (5) ensure a fair return to the public; and (6) preserve and maintain free enterprise competition.

Regulations at 30 CFR 582 implement these statutory requirements. There has been no activity in the OCS for minerals other than oil, gas and sulphur for many years; however, because these are regulatory requirements, the potential exists for information to be collected. Therefore, we are renewing OMB approval for this information collection.

We will use the information required by 30 CFR 582 to determine if lessees are complying with the regulations that implement the mining operations program for minerals other than oil, gas, and sulphur. BOEM will also use the information to ensure that such operations are conducted in a manner that will result in orderly resource recovery, development, and the protection of the human, marine, and coastal environments and for technical and environmental evaluations which provide a basis for BOEM to make informed decisions to approve, disapprove, or require modification of the proposed activities.

We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR 2), and 30 CFR 582.5, and 582.6 and applicable sections of 30 CFR parts 580 and 581. No items of a sensitive nature are collected. Responses are mandatory.

Frequency: Monthly; quarterly; on occasion.

Estimated Number and Description of Respondents: As there are no active respondents, we estimated the potential annual number of respondents to be one. Potential respondents are OCS lessees.

Estimated Reporting and Recordkeeping Hour Burden: We expect the burden estimate for the renewal will be 212 hours. This submission also removes the requirements and burdens that were transferred to the responsibility of the Bureau of Safety and Environmental Enforcement under Secretarial Order No. 3299, May 19, 2010. The following table details the individual BOEM components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

BURDEN TABLE

Citation 30 CFR 582	Reporting or recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
Subpart A—General				
4; 21(b)	Governors, other Federal/State agencies, lessees, interested parties, and others review and provide comments/recommendations on all plans and environmental information.	10	1	10
4(b); 12(b)(2); 21; 22; 25; 26; 28	Submit delineation plan, including environmental information, contingency plan, monitoring program, and various requests for approval referred to throughout; submit modifications and required information.	40	1	40

BURDEN TABLE—Continued

Citation 30 CFR 582	Reporting or recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
4(c); 12(c)(2); 21; 23; 25; 26; 28	Submit testing plan, including environmental information, contingency plan, monitoring program, and various requests for approval referred to throughout; submit modifications and required information.	40	1	40
4(d); 12(d)(2); 21; 24; 25; 26; 28	Submit mining plan, including environmental information, contingency plan, monitoring program, and various requests for approval referred to throughout; submit modifications and required information.	40	1	40
5	Request non-disclosure of G&G info.; provide consent; demonstrate loss of competitive position.	10	1	10
6	Governors of adjacent States request proprietary data, samples, etc., and disclosure agreement with BOEM.	10	1	10
7	Governor of affected State initiates negotiations on jurisdictional controversy, etc., and enters agreement with BOEM.	10	1	10
Subtotal			7 Responses	160
Subpart B—Jurisdiction and Responsibilities of Director				
11(c); 20(h); 30	Apply for right-of-use and easement; submit confirmations, demonstrations, notifications.	30	1	30
11(d)	Request consolidation/splitting of two or more OCS mineral leases or portions.	1	1	1
20(h)	Request approval of operations or departure from operating requirements.	Burden included with applicable plans		0
14	Submit response copy of form BOEM–1832 indicating date violations (INCs) corrected.	2	1	2
Subtotal			3 Responses	33
Subpart C—Obligations and Responsibilities of Lessees				
20(a), (g); 29(i)	Make available all mineral resource or environmental data and information; submit reports and maintain records, as specified.	Burden included with individual reporting requirements below		0
20(b) thru (e)	Submit designation of payor, operator, or local representative; submit changes, terminations, notifications.	1	1	1
21(d)	Notify BOEM of preliminary activities	1	1	1
29(a)	Submit monthly report of minerals produced; request extension.	1	1	1
29(b), (c)	Submit quarterly status and final report on exploration and/or testing activities.	5	1	5
29(d)	Submit results of environmental monitoring activities	5	1	5
29(e)	Submit marked and certified maps annually or as required.	1	1	1
29(f)	Maintain rock, minerals, and core samples for 5 years and make available upon request.	1	1	1
29(g)	Maintain original data and information and navigation tapes as long as lease is in effect and make available upon request.	1	1	1

BURDEN TABLE—Continued

Citation 30 CFR 582	Reporting or recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
29(h)	Maintain hard mineral records and make available upon request.	1	1	1
Subtotal			9 Responses	17
Subpart D—Payments				
40	Submit surety, personal bond, or approved alternative.	2	1 Response	2
Subpart E—Appeals				
50; 15	File an appeal	Burden exempt under 5 CFR 1320.4(a)(2), (c).		0
TOTAL BURDEN			20 Responses	212

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: There are no non-hour cost burdens associated with this collection.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, et seq.) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .''. Agencies must specifically solicit comments on: (a) Whether or not the collection of information is necessary, including whether or not the information will have practical utility; (b) the accuracy of the burden estimates; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden on respondents.

Agencies must also estimate the non-hour cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup costs or annual operation, maintenance, and purchase of service costs. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information, monitoring, and record storage facilities. You should not include estimates for equipment or services purchased: (a) Before October 1, 1995; (b) to comply with requirements not associated with the information collection; (c) for reasons other than to provide information or keep records for the Government; or (d) as part of customary and usual business or private practices.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: February 19, 2014.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulations, and Analysis.

[FR Doc. 2014–04121 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Gulf of Mexico, Outer Continental Shelf (OCS), Eastern Planning Area (EPA) Oil and Gas Lease Sales 225 and 226

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Availability (NOA) of a Record of Decision (ROD) for EPA Lease Sale 225 in the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2014–2016; Eastern Planning Area Lease Sales 225 and 226; Final Environmental Impact Statement* (EPA 225/226 EIS).

SUMMARY: BOEM has prepared a ROD for oil and gas EPA Lease Sale 225 scheduled for March 19, 2014. The proposed lease sale is in the Gulf of Mexico's EPA off the States of Louisiana, Mississippi, Alabama, and Florida. EPA Lease Sale 225 is the first EPA lease sale scheduled in the OCS Oil & Gas Leasing Program for 2012–2017 (Five Year Program). In making its decision, BOEM considered an alternative to the proposed action, the potential impacts as presented in the EPA 225/226 EIS, and all comments received throughout the NEPA process. The EPA 225/226 EIS evaluated the environmental and socioeconomic impacts for EPA Lease Sale 225.

SUPPLEMENTARY INFORMATION: In the EPA 225/226 EIS, BOEM evaluated two alternatives that are summarized below:

Alternative A—The Proposed Action: This is BOEM's preferred alternative. This alternative would offer for lease all unleased blocks within the proposed EPA lease sale area for oil and gas operations.

The EPA proposed lease sale area covers approximately 657,905 acres (approximately 175 whole and partial blocks) and includes those blocks previously included in the EPA Lease Sale 224 Area and a triangular-shaped area south of the EPA Lease Sale 224 area. The EPA proposed lease sale area is currently bordered to the north by the southern boundary of the Sale 181 area, to the west and south by the CPA boundary, and to east by the Military Mission Line (86°41′ W. longitude). The nearest point of land is about 125 mi (201 km) northwest in Louisiana. As of November 2013, approximately 465,200 acres of the proposed EPA lease sale area are currently unleased. The estimated amount of natural resources projected to be developed as a result of a proposed EPA lease sale is 0–0.071 billion barrels of oil and 0–0.162 trillion cubic feet of gas.

Alternative B—No Action: This alternative is the cancellation of proposed EPA Lease Sale 225 and is identified as the environmentally preferred alternative.

After careful consideration, BOEM has selected the proposed action, identified as BOEM's preferred alternative (Alternative A) in the EPA 225/226 EIS. BOEM's selection of the preferred alternative meets the purpose and need for the action, as identified in the EPA 225/226 EIS, and reflects an orderly resource development with protection of the human, marine, and coastal environments, while also ensuring that the public receives an equitable return for these resources and that free-market competition is maintained.

Record of Decision Availability: To obtain a single printed or CD–ROM copy of the ROD for proposed EPA Lease Sale 225, you may contact BOEM, Gulf of Mexico OCS Region, Public Information Office (GM 335A), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 (1–800–200–GULF). An electronic copy of the ROD is available on BOEM's Internet Web site at *http://boem.gov/Environmental-Stewardship/Environmental-Assessment/NEPA/nepaprocess.aspx*.

FOR FURTHER INFORMATION CONTACT: For more information on the ROD, you may contact Mr. Gary D. Goeke, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard (GM 623E), New Orleans, Louisiana 70123–2394. You may also contact Mr. Goeke by telephone at (504) 736–3233.

Authority: This NOA is published pursuant to the regulations (40 CFR part 1503) implementing the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Dated: February 11, 2014.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2014–04184 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Gulf of Mexico, Outer Continental Shelf (OCS), Central Planning Area (CPA) Oil and Gas Lease Sale 231

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Availability (NOA) of a Record of Decision (ROD) for CPA Lease Sale 231 in the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2013–2014; Western Planning Area Lease Sale 233, and Central Planning Area Lease Sale 231; Final Supplemental Environmental Impact Statement* (WPA 233/CPA 231 Supplemental EIS).

Authority: This NOA is published pursuant to the regulations (40 CFR part 1506) implementing the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*).

SUMMARY: BOEM has prepared a ROD for oil and gas CPA Lease Sale 231 scheduled for March 19, 2014. CPA Lease Sale 231 is the second CPA lease sale scheduled in the Outer Continental Shelf Oil & Gas Leasing Program for 2012–2017 (Five-Year Program). The proposed lease sale is in the Gulf of Mexico's CPA off the States of Louisiana, Alabama, and Mississippi. In making its decision, BOEM considered alternatives to the proposed action and the potential impacts as presented in the WPA 233/CPA 231 Supplemental EIS and all comments received throughout the NEPA process. The WPA 233/CPA 231 Supplemental EIS updated the baseline conditions and potential environmental effects of oil and natural gas leasing, exploration, development, and production in the WPA and CPA since publication of the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2012–2017; Western Planning Area Lease Sales 229, 233, 238, 246, and 248; Central Planning Area Lease Sales 227, 231, 235, 241, and 247, Final Environmental Impact Statement* (2012–2017 WPA/CPA Multisale EIS) (USDOI, BOEM, 2012b). The WPA 233/CPA 231 Supplemental EIS analyzed the potential impacts of the proposed action in the CPA and was completed in April 2013.

SUPPLEMENTARY INFORMATION: In the WPA 233/CPA 231 Supplemental EIS, BOEM evaluated three alternatives for CPA Lease Sale 231, which are summarized below:

Alternative A—The Proposed Action: This is BOEM's preferred alternative. This alternative would offer for lease all unleased blocks within the CPA for oil and gas operations, except whole and partial blocks deferred by the Gulf of Mexico Energy Security Act of 2006.

The proposed CPA lease sale area encompasses about 63 million acres of the total CPA area of 66.45 million acres. As of December 2013, approximately 40 million acres of the proposed CPA lease sale area are currently unleased. The estimated amount of resources projected to be developed as a result of proposed CPA Lease Sale 231 is 0.460–0.894 billion barrels of oil (BBO) and 1.939–3.903 trillion cubic feet (Tcf) of gas.

Alternative B—The Proposed Action Excluding the Unleased Blocks Near Biologically Sensitive Topographic Features: This alternative would offer for lease all unleased blocks within the proposed CPA lease sale area, as described for the proposed action (Alternative A), with the exception of any unleased blocks subject to the Topographic Features Stipulation.

Alternative C—No Action: This alternative is the cancellation of proposed CPA Lease Sale 231 and is identified as the environmentally preferred alternative.

After careful consideration, BOEM has selected a subset of the proposed action, (a portion of the lease sale area analyzed in Alternative A) in the WPA 233/CPA 231 Supplemental EIS. As noted in its Record of Decision, BOEM has decided to hold CPA Lease Sale 231 and offer for lease all unleased blocks in the CPA, except: (1) whole and partial of blocks deferred by the Gulf of Mexico Energy Security Act of 2006; (2) blocks that are adjacent or beyond the United States Exclusive Economic Zone in the area known as the northern portion of the Eastern Gap; and (3) whole and partial blocks that lie within the 1.4 nautical mile buffer zone north of the Continental Shelf Boundary between the United States and Mexico. BOEM's selection of a subset of the preferred alternative reflects an orderly resource development with protection of the human, marine, and coastal environments, while also ensuring that the public receives an equitable return for these resources and that free-market competition is maintained.

Record of Decision Availability: To obtain a single printed or CD–ROM copy of the ROD for proposed CPA Lease Sale 231, you may contact the BOEM, Gulf of Mexico OCS Region, Public Information Office (GM 335A), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 (1–800–200–GULF). An electronic copy of the ROD is available on BOEM's Internet Web site at *http://boem.gov/Environmental-Stewardship/Environmental-Assessment/NEPA/nepaprocess.aspx.*

FOR FURTHER INFORMATION CONTACT: For more information on the ROD, you may contact Mr. Gary D. Goeke, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard (GM 623E), New Orleans, Louisiana 70123–2394. You may also contact Mr. Goeke by telephone at (504) 736–3233.

Dated: February 13, 2014.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2014–04187 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[123R5065C6; RX.59589805.1002000; RR85818000]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation intends to seek approval of the following proposed new information collection: Collection and Compilation of Water Pipeline Field Performance Data. Before submitting the information collection request to the Office of Management and Budget for approval, the Bureau of Reclamation is soliticing public comments on this information collection.

DATES: Submit written comments on the information collection on or before *April 28, 2014.*

ADDRESSES: Send all written comments concerning this notice to Lee Sears, Materials Engineering Research Laboratory, 86–68180, Bureau of Reclamation, P.O. Box 25007, Denver, Colorado, 80225; or via email to *lsears@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: To request more information on this information collection or to request a copy of the collection instrument, please contact Lee Sears at 303–445–2392.

SUPPLEMENTARY INFORMATION:

I. Abstract

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), this notice announces that the Bureau of Reclamation has obtained the services of an outside entity to survey water facilities and collect data on water pipeline corrosion related failures. The information requested is required to comply with a request from Congress for the Bureau of Reclamation to assemble data on pipeline reliability for specific types of pipes.

II. Data

Title: Collection and Compilation of Water Pipeline Field Performance Data.

OMB Control Number: 1006–XXXX.

Description of respondents: Drinking water utility and Federal facility pipe data managers.

Frequency: One-time collection.

Estimated completion time: 3 minutes (making participation decision); 15 minutes (online survey); 2 minutes (online refusal survey); 60 minutes (uploading data); and 2 minutes (data upload refusal survey).

Estimated Total Number of Respondents: 418 (making participation decision); 209 (online survey); 209 (online refusal survey); 68 (uploading data); and 68 (data upload refusal survey).

Estimated Number of Responses per Respondent: 1.

Estimated Total of Annual Responses: 418 (making participation decision); 209 (online survey); 209 (online refusal survey); 68 (uploading data); and 68 (data upload refusal survey).

Estimated Total Annual Burden Hours on Respondents: 21 hours (making participation decision); 53 hours (online survey); 7 hours (online refusal survey); 68 hours (uploading data); and 3 hours (data upload refusal survey), for a combined total of 152 hours.

III. Request for Comments

We invite your comments on:

(a) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical use;

(b) the accuracy of our burden estimate for the proposed collection of information;

(c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

We will summarize all comments received regarding this notice. We will publish that summary in the **Federal Register** when the information collection request is submitted to OMB for review and approval.

IV. Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Date: February 20, 2014.

Richard W. LaFond,

Chief, Civil Engineering Services Division, Bureau of Reclamation.

[FR Doc. 2014–04145 Filed 2–25–14; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Availability of Funds and Solicitation for Grant Applications for H–1B Ready to Work Partnership Grants

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Solicitation for Grant Applications (SGA).

Funding Opportunity Number: SGA/DFA PY–13–07

SUMMARY: The Employment and Training Administration (ETA), U.S. Department of Labor (the Department), announces the availability of approximately $150 million in funds for the H–1B Ready to Work Partnership (Ready to Work) grant program. The Department expects to fund approximately 20–30 grants with individual grant amounts ranging from $3 million to $10 million. This grant program is designed to provide long-term unemployed workers with individualized counseling, training and supportive and specialized services leading to rapid employment in skilled occupations and industries for which employers use H–1B visas to hire foreign workers. A small percentage of

other unemployed and/or incumbent workers may also be served through this program. These grants are financed by a user fee paid by employers to bring foreign workers into the United States under the H–1B nonimmigrant visa program. This program was authorized under Section 414(c) of the American Competitiveness and Workforce Improvement Act of 1998 (ACWIA), as amended (29 U.S.C. 2916a). Grant awards will be made only to the extent that funds are available.

Grants will be awarded to the lead applicant of a public and private partnership of entities that includes: the workforce investment system; training providers, such as community colleges and community-based and faith-based organizations; and, business and business-related groups, trade associations, nonprofit business or industry, organizations functioning as workforce intermediaries for the expressed purpose of serving the needs of businesses, individual businesses, or consortia of businesses.

The complete SGA and any subsequent SGA amendments in connection with this solicitation are described in further detail on ETA's Web site at *http://www.doleta.gov/grants/* or on *http://www.grants.gov.* The Web sites provide application information, eligibility requirements, review and selection procedures, and other program requirements governing this solicitation.

DATES: The closing date for receipt of applications under this announcement is June 19, 2014. Applications must be received no later than 4:00:00 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT: Kia Mason, 200 Constitution Avenue NW., Room N–4716, Washington, DC 20210; Telephone: 202–693–2606.

Signed: February 20, 2014 in Washington, DC.

Eric D. Luetkenhaus,

Grant Officer, Employment and Training Administration.

[FR Doc. 2014–04037 Filed 2–25–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, 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. 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 requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed extension without change of a currently approved collection for the ''Producer Price Index'' survey. A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the Addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the Addresses section of this notice on or before April 28, 2014.

ADDRESSES: Send comments to Nora Kincaid, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Nora Kincaid, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Producer Price Index (PPI), one of the Nation's leading economic indicators, is used as a measure of price movements, as an indicator of inflationary trends, for inventory valuation, and as a measure of purchasing power of the dollar at the primary-market level. It also is used for market and economic research and as a basis for escalation in long-term contracts and purchase agreements.

Producer Price Index data provide a description of the magnitude and composition of price change within the economy, and serve a wide range of governmental needs. This family of indexes are closely followed, monthly statistics, which are viewed as sensitive indicators of the economic environment. Price data are vital in helping both the President and Congress set fiscal-spending targets. Producer prices are monitored by the Federal Reserve Board Open Market Committee to help decide monetary policy. Federal policy-makers at the Department of Treasury and the Council of Economic Advisors utilize these statistics to help form and evaluate monetary and fiscal measures and to help interpret the general business environment. In addition, it is common to find one or more PPIs, alone or in combination with other measures, used to escalate the delivered price of goods for government purchases.

In addition to governmental uses, PPI data are regularly put to use by the private sector. Private industry uses PPI data for contract escalation. For one particular method of tax-related Last-In-First-Out (LIFO) inventory accounting, the Internal Revenue Service suggests that firms use PPI data for making calculations. Private businesses make extensive use of industrial-price data for planning and operations. Price trends are used to assess the condition of markets. Firms commonly compare the prices they pay for material inputs as well as prices they receive for products that they make and sell with changes in similar PPIs.

Economic researchers and forecasters also put the PPI to regular use. PPIs are widely used to probe and measure the interaction of market forces. Some examples of research topics that require extensive price data include: the identification of varying price elasticities and the degree of cost pass-through in the economy, the identification of potential lead and lag structures among price changes, and the identification of prices which exert major impacts throughout market structures.

II. Current Action

Office of Management and Budget clearance is being sought for the Producer Price Index survey.

The PPI collection is not a one-time project with an end date. The purpose of the PPI collection is to accumulate data for the ongoing, monthly publication of the PPI family of indexes. The Bureau of Labor Statistics must continue collecting data for the PPI since both policy and business planning are affected by the completeness of the description of price trends. Dollar-denominated measures of economic performance, such as Gross Domestic Product, require accurate price data in order to convert nominal to constant-dollar values. Inflation-free national income accounting figures are vital to fiscal and monetary policy-makers when setting objectives and targets. It is conservatively estimated that hundreds-of-billions of dollars worth of contracts and purchase agreements employ PPIs as part of price-adjustment clauses.

Failure to calculate these data would tend to extend the time frame required for accurate recognition of and appropriate adaptation to economic events.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Type of Review: Extension without change of a currently approved collection.

Agency: Bureau of Labor Statistics.

Title: Producer Price Index Survey.

OMB Number: 1220–0008.

Affected Public: Private Sector.

Form	Total respondents	Frequency	Total responses	Average Time per response (minutes)	Estimated total burden (hours)
BLS 1810A, A1, B, C, C1, and E	5,836	once	5836	120	11,672
BLS 473P	26,250	monthly	* 1,260,000	5	105,000
Totals	32,086		1,265,386		116,672

* For monthly repricing, an average of 4 forms are sent to each respondent or on average PPI requests repricing of 105,000 items each month.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

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 also will become a matter of public record.

Signed at Washington, DC, this 20th day of February 2014.

Kimberley D. Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2014–04059 Filed 2–25–14; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (14–020)]

Notice of Intent To Grant a Partially Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant partially exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the inventions described and claimed in U.S. Patent No. 6,879,893 B2, ''Tributary Analysis Monitoring System,'' NASA Case No. LAR–16516–1; U.S. Patent No. 7,075,295 B2, ''Magnetic Field Response Sensor for Conductive Media,'' NASA Case No. LAR–16571–1; U.S. Patent No. 7,589,525 B2, ''Magnetic Field Response Sensor for Conductive Media,'' NASA Case No. LAR–16571–2; U.S. Patent No. 7,759,932 B2, ''Magnetic Field Response Sensor for Conductive Media,'' NASA Case No. LAR–16571–3; U.S. Patent No. 7,086,593 B2, ''Magnetic Field Response Measurement Acquisition System,'' NASA Case No. LAR–16908–1; U.S. Patent No. 7,159,774 B2, ''Magnetic Field Response Measurement Acquisition System,'' NASA Case No. LAR–17280–1; U.S. Patent No. 8,430,327 B2, ''Wireless Sensing System Using Open-Circuit, Electrically-Conductive Spiral-Trace Sensor,'' NASA Case No. LAR–17294–1; U.S. Patent No. 7,902,815 B2, ''Wireless System and Method for Collecting Motion and Non-Motion Related Data of a Rotating System,'' NASA Case No. LAR–17433–1; U.S. Patent No. 8,179,203 B2, ''Wireless Electrical Device Using Open-Circuit Elements Having No Electrical Connections,'' NASA Case No. LAR–17711–1; U.S. Patent Application No. 13/029,471, ''Wireless Temperature Sensing Having No Electrical Connections and Sensing Method for Use Therewith,'' NASA Case No. LAR–17747–1; and U.S. Patent Application No. 13/029,426, ''Wireless Temperature Sensing Having No Electrical Connections and Sensing Method for Use Therewith,'' NASA Case No. LAR–18016–1 to Par-Tech, Inc. having its principal place of business in Lake Orion, Michigan. The fields of use may be limited to, but not necessarily limited to, tire measurement and/or monitoring applications including the detection of pressure, temperature, wear and damage. The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: The prospective partially exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated partially exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30, (757) 864–3230 (phone), (757) 864–9190 (fax).

FOR FURTHER INFORMATION CONTACT: Robin W. Edwards, Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30, (757) 864–3230; Fax: (757) 864–9190. Information

about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Sumara M. Thompson-King,

Deputy General Counsel.

[FR Doc. 2014–04163 Filed 2–25–14; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meeting of National Council on the Humanities

AGENCY: National Endowment for the Humanities.

ACTION: Notice of Meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that the National Council on the Humanities will meet for the following purposes: To advise the Chairman of the National Endowment for the Humanities (NEH) with respect to policies, programs and procedures for carrying out his functions; to review applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended) and make recommendations thereon to the Chairman; and to consider gifts offered to NEH and make recommendations thereon to the Chairman.

DATES: The meeting will be held on Thursday and Friday, March 13–14, 2014, each day from 9:00 a.m. until adjourned.

ADDRESSES: The meeting will be held at the Old Post Office Building, 1100 Pennsylvania Ave. NW., Washington, DC 20506. See **SUPPLEMENTARY INFORMATION** section for room numbers.

FOR FURTHER INFORMATION CONTACT: Lisette Voyatzis, Committee Management Officer, 1100 Pennsylvania Ave. NW., Room 529, Washington, DC 20506, or call (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the National Endowment for the Humanities' TDD terminal at (202) 606–8282. Please provide advance notice of any special needs or accommodations, including for a sign language interpreter.

SUPPLEMENTARY INFORMATION: The Committee meetings of the National Council on the Humanities will be held on March 13, 2014, as follows: The policy discussion session (open to the public) will convene at 9:00 a.m. until approximately 10:30 a.m., followed by the discussion of specific grant applications and programs before the Council (closed to the public) from 10:30 a.m. until adjourned.

Digital Humanities: Room 402
Education Programs: Room M–07
Preservation and Access: Room 415
Public Programs & Federal/State Partnership: Room 507
Research Programs: Room 315

In addition, the Jefferson Lecture Committee (closed to the public) will meet from 2:00 p.m. until 3:00 p.m. in Room 527.

The Plenary Session of the National Council on the Humanities will convene on March 14, 2013 at 9:00 a.m. in Room M–09. The agenda for the morning session (open to the public) will be as follows:

A. Minutes of the Previous Meeting
B. Reports
1. Introductory Remarks
2. Film Presentation on NEH-funded project, ''The Scholar and The Sailor''
3. Staff Report
4. Chief of Staff/White House and Congressional Affairs Report
5. Budget Report
6. Reports on Policy and General Matters
a. Digital Humanities
b. Education Programs
c. Preservation and Access
d. Public Programs
e. Federal/State Partnership
f. Research Programs
g. Jefferson Lecture

The remainder of the Plenary Session will be for consideration of specific applications and therefore will be closed to the public.

As identified above, portions of the meeting of the National Council on the Humanities will be closed to the public pursuant to sections 552b(c)(4), 552b(c)(6) and 552b(c)(9)(b) of Title 5 U.S.C., as amended. The closed sessions will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, and discussion of certain information, the premature disclosure of which could significantly frustrate implementation of proposed agency action. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated July 19, 1993.

Dated: February 20, 2014.

Lisette Voyatzis,

Committee Management Officer.

[FR Doc. 2014–04193 Filed 2–25–14; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on US–APWR

Notice of Meeting

The ACRS Subcommittee on US–APWR will hold a meeting on March 4, 2014, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance with the exception of portions that may be closed to protect information that is propriety pursuant to 5 U.S.C. 552(c)(4). The agenda for the subject meeting shall be as follows:

Tuesday, March 4, 2014—8:30 a.m. Until 5:00 p.m.

The Subcommittee will review Chapter 14, ''Verification Programs,'' of the Safety Evaluation Report (SER) associated with the US–APWR design certification and the Comanche Peak Combined License Application (COLA). The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, Mitsubishi Heavy Industries, Luminant Generation Company, LLC, 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), Girija Shukla (Telephone 301–415–6855 or Email: *Girija.Shukla@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 November 8, 2013, (78 CFR 67205–67206).

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: February 20, 2014.

Cayetano Santos,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2014–04207 Filed 2–25–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS)

Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on March 5, 2014, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, March 5, 2014—12:00 p.m. Until 1:00 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. 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), Quynh Nguyen (Telephone 301–415–5844 or Email: *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that 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 November 8, 2013, (78 CFR 67205–67206).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained 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 the DFO 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 (240–888–9835) to be escorted to the meeting room.

Dated: February 20, 2014.

Cayetano Santos,

Chief Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2014–04209 Filed 2–25–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–333; NRC–2014–0034]

James A. FitzPatrick Nuclear Power Plant, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: 10 CFR 2.206 request; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is giving notice that by petition dated July 25, 2013, David L. Lochbaum, on behalf of the Alliance for Green Economy, Beyond Nuclear, Citizen's Awareness Network, and Union of Concerned Scientists (together referred to as petitioners) has requested that the NRC take enforcement action with regard to James A. FitzPatrick Nuclear Power Plant. The petitioners' requests are included in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Please refer to Docket ID NRC–2014–0034 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0034. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov*.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library 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 in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *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.

SUPPLEMENTARY INFORMATION: On July 25, 2013, the petitioners requested that the NRC take action with regard to James A. FitzPatrick Nuclear Power Plant (ADAMS Accession No. ML13217A061). The petitioners requested that the NRC take enforcement action by imposing a regulatory requirement that all the tubes in the James A. FitzPatrick Nuclear Power Plant's condenser be replaced prior to the restart of the plant from its fall 2014 refueling outage.

As the basis for this request, the petitioners stated that the enforcement action is needed to protect the public from the owner of the plant opting to defer correcting a potential safety problem. James A. Fitzpatrick Nuclear Power Plant is experiencing abnormally

high occurrences of condenser tube failures. The condenser tube leaks could cause the normal heat sink to become unavailable, which in turn can complicate the operator's response to a reactor shutdown. The petitioners pointed out that the NRC's reactor oversight process also recognizes the elevated risk associated with a reactor shutdown with complications. Operating experience indicates that condenser tube leaks have contaminated the reactor coolant with impurities from the condenser cooling water and caused extensive damage to nuclear power plant components. The petitioners explained their concerns with comparison of historical data of U.S plants' condenser tube leaks that showed that the James A. FitzPatrick Nuclear Power Plant has experienced over 30 percent of the condenser tube leak events of the entire U.S. fleet in the past decade.

The request is being treated pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.206 of the Commission's regulations. The request has been referred to the Director of the Office of Nuclear Reactor Regulation. As provided by 10 CFR 2.206, appropriate action will be taken on this petition within a reasonable time. The petitioner and the co-petitioners met with NRC's Petition Review Board (PRB) on November 13, 2013 (transcript at ADAMS Accession No. ML14036A234) to further discuss their concerns. The results of that discussion were considered in the board's determination regarding the petitioner's request for action and in establishing the schedule for the review of the petition. A copy of the petition is available for inspection under ADAMS Accession No. ML13217A061.

Dated at Rockville, Maryland, this 12th day of February 2014.

For the Nuclear Regulatory Commission.

Jennifer Uhle,

Deputy Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2014–04208 Filed 2–25–14; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension: Rule 17g–7, SEC File No. 270–600, OMB Control No. 3235–0656.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17g–7, (17 CFR 240.17g–7), under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17g–7 requires nationally recognized statistical rating organizations (''NRSROs'') to include in any report accompanying a credit rating with respect to an asset-backed security (''ABS'') (as that term is defined in Section 3(a)(77) of the Exchange Act) a description of the representations, warranties and enforcement mechanisms available to investors and a description of how they differ from the representations, warranties and enforcement mechanisms in issuances of similar securities. Rule 17g–7 potentially applies to each of the 10 NRSROs currently registered with the Commission.[1]

Commission staff estimates that the 10 currently-registered NRSROs would each spend an average of approximately 100 hours per year reviewing and updating benchmarks for various types of securities for purposes of comparing representations, warranties, and enforcement mechanisms, resulting in an annual industry-wide reporting burden of 1,000 hours (10 respondents × 100 hours/respondent). On a deal-by-deal basis, Commission staff estimates that it would take each NRSRO an average of approximately: (i) One hour to review each ABS transaction to review the relevant disclosures prepared by an issuer, which an NRSRO would review as part of the rating process, and convert those disclosures into a format suitable for inclusion in any report to be issued by an NRSRO, and (ii) 10 hours per ABS transaction to compare the terms of the current deal to those of similar securities. When the Commission adopted Rule 17g–7, it estimated the average annual number of ABS offerings to be 2,067 and the average number of credit ratings per issuance of ABS to be four, resulting in 8,268 annual responses.[2] Commission staff believes that these estimates continue to be valid and, accordingly, estimates that the total industry-wide annual reporting burden of complying with the disclosure requirements under Rule 17g–7 is 90,948 hours (8,268 responses × 11 hours/response). As a result, Commission staff estimates a total aggregate burden of 91,948 hours per year for complying with the rule (1,000 hours for reviewing and updating benchmarks + 90,948 hours for complying with disclosure requirements).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

[1] When the Commission first adopted rules under the Credit Rating Agency Reform Act of 2006, it estimated that approximately 30 credit rating agencies ultimately would be registered as NRSROs. *See Oversight of Credit Rating Agencies Registered as Nationally Recognized Statistical Rating Organizations,* Release No. 34–55857 (Jun. 5, 2007), 72 FR 33564, 33607 (Jun. 18, 2007). Accordingly, the Commission used 30 respondents for purposes of calculating its PRA burden estimates when it adopted Rule 17g–7. *See Disclosure for Asset-Backed Securities Required by Section 943 of the Dodd-Frank Wall Street Reform and Consumer Protection Act,* Release No. 33–9175; 34–63741 (Jan. 20, 2011), 76 FR 4489, 4506 (Jan. 26, 2011) (''Rule 17g–7 Adopting Release''). Since that time, 10 credit rating agencies have registered with the Commission as NRSROs. This number has remained constant for several years. Consequently, when the Commission last proposed rules regarding the oversight of NRSROs, it stated that it believed it to be more appropriate to use the actual number of NRSROs for purposes of the PRA. *See Proposed Rules for Nationally Recognized Statistical Rating Organizations,* Release No. 34–64514 (May 18, 2011), 76 FR 33420, 33499 (Jun. 8, 2011) (stating that ''while the Commission expects several more credit rating agencies may become registered as NRSROs over the next few years, the Commission preliminarily believes that the actual number of NRSROs should be used for purposes of the PRA.'').

[2] *See Rule 17g–7 Adopting Release,* 76 FR at 4508.

Dated: February 19, 2014.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–04131 Filed 2–25–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71588; File No. SR–NYSEArca–2014–10]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To Adopt NYSE Arca Equities Rule 8.900, Which Permits the Listing and Trading of Managed Portfolio Shares, and To List and Trade Shares of the ActiveShares^{SM} Large-Cap Fund, ActiveShares^{SM} Mid-Cap Fund, and ActiveShares^{SM} Multi-Cap Fund Pursuant to That Rule

February 20, 2014.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on February 7, 2014, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I 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 to adopt new NYSE Arca Equities Rule 8.900 to permit it to list and trade Managed Portfolio Shares, which are shares of actively managed exchange-traded funds (''ETFs'') for which the portfolio is disclosed quarterly. In addition, the Exchange proposes to list and trade shares of the following under proposed NYSE Arca Equities Rule 8.900: ActiveShares^{SM} Large-Cap Fund; ActiveShares^{SM} Mid-Cap Fund; and ActiveShares^{SM} Multi-Cap Fund.

The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 to add new NYSE Arca Equities Rule 8.900 for the purpose of permitting the listing and trading, or trading pursuant to unlisted trading privileges (''UTP''), of Managed Portfolio Shares, which are securities issued by an actively managed open-end investment management company.[4] The Exchange also proposes to amend NYSE Arca Equities Rule 7.34 (Trading Sessions) to reference securities described in proposed NYSE Arca Equities Rule 8.900 in Rule 7.34(a)(4)(A) relating to trading halts for trading pursuant to UTP during the Exchange's Opening Session.

In addition to the above-mentioned proposed rule changes, the Exchange proposes to list and trade shares (''Shares'') of the following under proposed NYSE Arca Equities Rule 8.900: ActiveShares^{SM} Large-Cap Fund; ActiveShares^{SM} Mid-Cap Fund; and ActiveShares^{SM} Multi-Cap Fund (each a ''Fund'' and, collectively, the ''Funds'').

Proposed Listing Rules

Proposed Rule 8.900(a) provides that the Corporation will consider for trading, whether by listing or pursuant to UTP, Managed Portfolio Shares that meet the criteria of Rule 8.900.

[4] A Managed Portfolio Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(3) (''Index ETFs''), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

Proposed Rule 8.900(b) provides that Rule 8.900 is applicable only to Managed Portfolio Shares and that, except to the extent inconsistent with Rule 8.900, or unless the context otherwise requires, the rules and procedures of the Corporation's Board of Directors shall be applicable to the trading on the Corporation of such securities. Proposed Rule 8.900(b) provides further that Managed Portfolio Shares are included within the definition of ''security'' or ''securities'' as such terms are used in the Rules of the Corporation.

Proposed Definitions. Proposed Rule 8.900(c)(1) defines the term ''Managed Portfolio Share'' as a security that (a) is issued by a registered investment company (''Investment Company'') organized as an open-end management investment company or similar entity, that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in any size amount for a cash amount equal to the next determined net asset value (''NAV''); (c) may be redeemed for cash by any Retail Investor (as defined below) in any size less than a Redemption Unit (as defined below) for a cash amount equal to the next determined NAV; and (d) when aggregated in a number of shares equal to a Redemption Unit or multiples thereof, may be redeemed at a holder's request, which holder will be paid though a blind trust established for its benefit a portfolio of securities and/or cash with a value equal to the next determined NAV.

Proposed Rule 8.900(c)(2) defines the term ''Retail Investor'' as (i) a natural person; (ii) a trust established exclusively for the benefit [sic] a natural person or a group of related family members; or (iii) a tax deferred retirement plan where investments are selected by a natural person purchasing for its own account.

Proposed Rule 8.900(c)(3) defines the term ''Portfolio Indicative Value'' as the estimated indicative value of an Managed Portfolio Share based on all of the issuer's holdings as of the close of business on the prior business day.

Proposed Rule 8.900(c)(4) defines the term ''Redemption Unit'' as a specified number of Managed Portfolio Shares used for determining whether a Retail Investor may redeem for cash.

Proposed Rule 8.900(c)(5) defines the term [sic]Reporting Authority'' in respect of a particular series of Managed Portfolio Shares as a reporting service designated by the issuer and acceptable to the Corporation or by the exchange

that lists a particular series of Managed Portfolio Shares (if the Corporation is trading such series pursuant to UTP) as the official source for calculating and reporting information relating to such series, including, but not limited to, the Portfolio Indicative Value, NAV, or other information relating to the issuance, redemption or trading of Managed Portfolio Shares. A series of Managed Portfolio Shares may have more than one Reporting Authority, each having different functions.

Proposed Rule 8.900(d) sets forth initial and continued listing criteria applicable to Managed Portfolio Shares. Proposed Rule 8.900(d)(1) provides that, for each series of Managed Portfolio Shares, the Corporation will establish a minimum number of Managed Portfolio Shares required to be outstanding at the time of commencement of trading on the Corporation. In addition, the Corporation will obtain a representation from the issuer of each series of Managed Portfolio Shares that the NAV per share for the series will be calculated daily and that the NAV will be made available to all market participants at the same time.[5]

Proposed Rule 8.900(d)(2) provides that each series of Managed Portfolio Shares will be listed and traded subject to application of the following continued listing criteria. Proposed Rule 8.900(d)(2)(A) provides that the Portfolio Indicative Value for Managed Portfolio Shares will be widely disseminated by one or more major market data vendors at least every 15 seconds during Core Trading Session.

Proposed Rule 8.900(d)(2)(B) provides that the Corporation will consider the suspension of trading in or removal from listing of a series of Managed Portfolio Shares under any of the following circumstances: (i) if, following the initial twelve-month period after commencement of trading on the Exchange of a series of Managed Portfolio Shares, there are fewer than 50 beneficial holders of the series of Managed Portfolio Shares for 30 or more consecutive trading days; (ii) if the value of the Portfolio Indicative Value is no longer calculated or made available to all market participants at the same time; (iii) if the Investment Company issuing the Managed Portfolio Shares has failed to file any filings required by the Commission or if the Corporation is aware that the Investment Company is not in compliance with the conditions of any exemptive order or no-action relief granted by the Commission to the Investment Company with respect to the series of Managed Portfolio Shares; or (iv) if such other event shall occur or condition exists which, in the opinion of the Corporation, makes further dealings on the Corporation inadvisable.

Proposed Rule 8.900(d)(2)(C) provides that, if the Portfolio Indicative Value of a series of Managed Portfolio Shares is not being disseminated as required, the Corporation may halt trading during the day in which the interruption to the dissemination of the Portfolio Indicative Value occurs. If the interruption to the dissemination of the Portfolio Indicative Value persists past the trading day in which it occurred, the Corporation will halt trading no later than the beginning of the trading day following the interruption. If a series of Managed Portfolio Shares is trading on the Corporation pursuant to UTP, the Corporation will halt trading in that series as specified in Rule 7.34(a). In addition, if the Exchange becomes aware that the NAV with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time, it will halt trading in such series until such time as the NAV is available to all market participants.

Proposed Rule 8.900(d)(2)(D) provides that, upon termination of an Investment Company, the Corporation requires that Managed Portfolio Shares issued in connection with such entity be removed from Corporation listing.

Proposed Rule 8.900(d)(2)(E) provides that voting rights shall be as set forth in the applicable Investment Company prospectus. Proposed Rule 8.600(e) relates to limitation of Corporation liability.

Proposed Rule 8.900(e), which relates to limitation of corporation liability, provides that neither the Corporation, the Reporting Authority, nor any agent of the Corporation shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current portfolio value; the current value of the portfolio of securities required to be deposited to the open-end management investment company in connection with issuance of Managed Portfolio Shares; the amount of any dividend equivalent payment or cash distribution to holders of Managed Portfolio Shares; NAV; or other information relating to the purchase, redemption, or trading of Managed Portfolio Shares, resulting from any negligent act or omission by the Corporation, the Reporting Authority or any agent of the Corporation, or any act, condition, or cause beyond the reasonable control of the Corporation, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

Proposed Commentary .01 to NYSE Arca Equities Rule 8.900 provides that the Corporation will file separate proposals under Section 19(b) of the Act before the listing and trading of Managed Portfolio Shares. Proposed Commentary .02 to NYSE Arca Equities Rule 8.900 provides that transactions in Managed Portfolio Shares will occur during the trading hours specified in NYSE Arca Equities Rule 7.34(a).

Proposed Commentary .03 to NYSE Arca Equities Rule 8.900 provides that the Exchange will implement written surveillance procedures for Managed Portfolio Shares.

Proposed Commentary .04 to NYSE Arca Equities Rule 8.900 provides that Authorized Participants (as described further below) redeeming Managed Portfolio Shares will sign an agreement with the applicable fund requiring the establishment of a blind trust for the benefit of such Authorized Participant that will receive all consideration from the issuer in a redemption, which blind trust will be bound not to disclose the consideration received in a redemption except as required by law and will liquidate any securities received in a redemption in accordance with standing instructions for the Authorized Participant.

Proposed Commentary .05 to NYSE Arca Equities Rule 8.900 provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. Personnel who make decisions on the Investment Company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio.

[5] NYSE Arca Equities Rule 7.34(a)(5) (''Trading Halts of Derivative Securities Products Listed on the NYSE Arca Marketplace)'' provides that, with respect to Derivative Securities Products listed on the NYSE Arca Marketplace for which a net asset value is disseminated, if the Exchange becomes aware that the a net asset value is not being disseminated to all market participants at the same time, it will halt trading in the affected Derivative Securities Product on the NYSE Arca Marketplace until such time as the a net asset value is available to all market participants.

Other Rules

The Exchange proposes to amend NYSE Arca Equities Rule 7.34(a)(4) to include Managed Portfolio Shares under ''Derivative Securities Products'' for purposes of Rule 7.34(a)(4) relating to trading halts for trading pursuant to UTP of Derivative Securities Products on the Exchange.[6]

Key Features of Managed Portfolio Shares

While funds issuing Managed Portfolio Shares will be actively-managed and, to that extent, will be similar to Managed Fund Shares, Managed Portfolio Shares differ from Managed Fund Shares in the following important respects. First, in contrast to Managed Fund Shares, which are actively-managed funds listed and traded under NYSE Arca Equities Rule 8.600[7] and for which a ''Disclosed Portfolio'' is required to be disseminated at least once daily,[8] the portfolio for an issue of Managed Portfolio Shares will be disclosed quarterly in accordance with normal disclosure requirements otherwise applicable to open-end investment companies registered under the 1940 Act.[9] Second, in connection with the redemption of shares in Redemption Unit size, the delivery of any portfolio securities in kind will generally be effected through a blind trust for the benefit of the redeeming Authorized Participant and the blind trust will liquidate the portfolio securities without disclosing the identity of such securities to the Authorized Participant. Third, as with traditional open-end investment companies, retail investors will be able to redeem shares for cash directly from a fund on any day and in any size less than a Redemption Unit at the fund's NAV, as described in more detail below. Fourth, investors will be able to purchase shares for cash directly from a fund in any amount on any day a fund determines its NAV, as described in more detail below. Investors may choose to purchase shares directly from a fund if they want to assure that they will not purchase shares at a premium.

For each series of Managed Portfolio Shares, an estimated value, defined in the proposed rules as the ''Portfolio Indicative Value,'' (''PIV'') that reflects an estimated intraday value of a fund's portfolio will be disseminated. The PIV will be based upon all of a fund's holdings as of the close of the prior business day and will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session (normally, 9:30 a.m. to 4:00 p.m., Eastern Time). The dissemination of the PIV will allow investors to determine the estimated intra-day value of the underlying portfolio of a series of Managed Portfolio Shares on a daily basis and will provide a close estimate of that value throughout the trading day. The PIV should not be viewed as a ''real-time'' update of the NAV per share of each fund because the PIV may not be calculated in the same manner as the NAV, which will be computed once a day, generally at the end of the business day. Unlike the PIV, which will be based on consolidated last sale information, the NAV per share will be based on the closing price on the primary market for each portfolio security. If there is no closing price for a particular portfolio security, such as when it [sic] the subject of a trading halt, a fund will use fair value pricing. That fair value pricing will be carried over to the next day's PIV until the first trade in that stock is reported.

The Exchange, after consulting with various Lead Market Makers that trade ETFs on the Exchange, believes that market makers will be able to make efficient and liquid markets priced near the PIV as long as an accurate PIV is disseminated every 15 seconds and market makers have knowledge of a fund's means of achieving its investment objective, even without daily disclosure of a fund's underlying portfolio. The Exchange believes that market makers will employ risk-management techniques such as ''statistical arbitrage'', which is currently used throughout the financial services industry, to make efficient markets in exchange-traded products.[10] This ability should permit market makers to make efficient markets in an issue of Managed Portfolio Shares without knowledge of a fund's underlying portfolio.

The Exchange understands that traders use statistical analysis to derive correlations between different sets of instruments to identify opportunities to buy or sell one set of instruments when it is mispriced relative to the others. For Managed Portfolio Shares, market makers will initially use the knowledge of a fund's means of achieving its investment objective, as described in the applicable fund registration statement, to construct a hedging proxy for a fund to manage a market maker's quoting risk in connection with trading fund shares. Market makers will then conduct statistical arbitrage between their hedging proxy (for example, the Russell 1000 Index) and shares of a fund, buying and selling one against the other over the course of the trading day,[sic] They will evaluate how their proxy performed in comparison to the price of a fund's shares, and use that analysis as well as knowledge of risk metrics, such as volatility and turnover, to enhance their proxy calculation to make it a more efficient hedge.

Market makers have indicated to the Exchange that, after the first few days of trading, there will be sufficient data to run a statistical analysis which will lead to spreads being tightened substantially around the PIV. This is similar to certain other existing exchange traded products (for example, ETFs that invest

[6] The Exchange will propose applicable NYSE Arca Equities listing fees for Managed Portfolio Shares in the NYSE Arca Equities Schedule of Fees and Charges via a separate proposed rule change.

[7] The Commission has previously approved listing and trading on the Exchange of a number of issues of Managed Fund Shares under Rule 8.600. *See, e.g.,* Securities Exchange Act Release Nos. 57801 (May 8, 2008), 73 FR 27878 (May 14, 2008) (SR–NYSEArca–2008–31) (order approving Exchange listing and trading of twelve actively-managed funds of the WisdomTree Trust); 60460 (August 7, 2009), 74 FR 41468 (August 17, 2009) (SR–NYSEArca–2009–55) (order approving listing of Dent Tactical ETF); 63076 (October 12, 2010), 75 FR 63874 (October 18, 2010) (SR–NYSEArca–2010–79) (order approving Exchange listing and trading of Cambria Global Tactical ETF); 63802 (January 31, 2011), 76 FR 6503 (February 4, 2011) (SR–NYSEArca–2010–118) (order approving Exchange listing and trading of the SiM Dynamic Allocation Diversified Income ETF and SiM Dynamic Allocation Growth Income ETF).

[8] NYSE Arca Equities Rule 8.600(c)(2) defines the term ''Disclosed Portfolio'' as the identities and quantities of the securities and other assets held by the Investment Company that will form the basis for the Investment Company's calculation of net asset value at the end of the business day. NYSE Arca Equities Rule 8.600(d)(2)(B)(i) requires that the Disclosed Portfolio will be disseminated at least once daily and will be made available to all market participants at the same time.

[9] A mutual fund is required to file with the Commission its complete portfolio schedules for the second and fourth fiscal quarters on Form N–SAR under the 1940 Act, and is required to file its complete portfolio schedules for the first and third fiscal quarters on Form N–Q under the 1940 Act, within 60 days of the end of the quarter. Form N–Q requires funds to file the same schedules of investments that are required in annual and semi-annual reports to shareholders. These forms are available to the public on the Commission's Web site at *www.sec.gov.*

[10] Statistical arbitrage enables a trader to construct an accurate proxy for another instrument, allowing it to hedge the other instrument or buy or sell the instrument when it is cheap or expensive in relation to the proxy. Statistical analysis permits traders to discover correlations based purely on trading data without regard to other fundamental drivers. These correlations are a function of differentials, over time, between one instrument or group of instruments and one or more other instruments. Once the nature of these price deviations have been quantified, a universe of securities is searched in an effort to, in the case of a hedging strategy, minimize the differential. Once a suitable hedging proxy has been identified, a trader can minimize portfolio risk by executing the hedging basket. The trader then can monitor the performance of this hedge throughout the trade period making correction [sic] where warranted.

in foreign securities that do not trade during U. S. trading hours), in which spreads may be generally wider in the early days of trading and then narrow as market makers gain more confidence in their real-time hedges.

Description of the Funds and the Trust

The Shares of each Fund will be issued by Precidian ETFs Trust (''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[11] The investment adviser to the Trust will be Precidian Funds LLC (the ''Adviser''). JPMorgan Chase Bank, N.A. (the ''Transfer Agent'', ''Administrator'', or ''Custodian'') will serve as the Funds' transfer agent, administrator and custodian. Foreside Fund Services, LLC (''Distributor'') will serve as the distributor of the Shares.

As noted above, proposed Commentary .05 to Rule 8.900 provides that, if the investment adviser to the investment company issuing Managed Portfolio Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[12] In addition, proposed Commentary .05 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund's portfolio. Proposed Commentary .05 to Rule 8.900 is similar to Commentary .03(a)(i) and (iii) to NYSE Arca Equities Rule 5.2(j)(3); however, Commentary .05 in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is not registered as a broker-dealer or affiliated with a broker-dealer.

In the event (a) the Adviser or any sub-adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer, or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

The portfolio for each Fund will consist primarily of stocks in the Russell 3000 Index and shares issued by other exchange-traded funds (''ETFs'') that invest primarily in shares of issuers in the Russell 3000 Index (which consists of stocks included in the Russell 1000 Index and the Russell 2000 Index).[13] All exchange-listed equity securities in which the Funds will invest will be listed and traded on U.S. national securities exchanges.

Description of the Funds

The ActiveShares[SM] Large Cap Fund

According to the Registration Statement, the Fund's investment objective will be long-term capital appreciation. The Fund will seek to achieve its objective by taking long and possibly short positions in equity securities or groups of equities that the Fund's portfolio managers believe will provide long term capital appreciation. The Fund normally will invest at least 80% of its net assets (plus borrowings for investment purposes) in stocks included in the Russell 1000 Index and ETFs that primarily invest in stocks in the Russell 1000 Index.

The Fund will target an overall net equity market exposure of between 70% to 130%. However, at times the portfolio managers may reduce market exposure to less than 70%.

The Fund will purchase securities that the portfolio managers believe are undervalued and sell short securities that the portfolio managers believe are overvalued. Under normal market conditions,[14] the Fund's net long equity market exposure will not exceed 130% and its net short equity market exposure will not exceed 30%; however, the portfolio managers may at times exceed these percentages. The Fund may hold a substantial portion of its total assets in cash or cash equivalents when it holds significant short positions.[15]

The Fund may use ETFs to manage the Fund's overall equity market and sector exposures. In particular, the portfolio managers may take long and short positions in ETFs to increase/decrease equity market/sector exposures in place of using individual equity securities. The ETFs in which the Fund will invest are registered investment companies that seek to track the performance of an underlying index. These underlying indexes include not only broad-based market indexes but

[11] The Trust will be registered under the 1940 Act. On January 22, 2014, the Trust filed a registration statement on Form N–1A under the Securities Act of 1933 (the ''1933 Act'') (15 U.S.C. 77a), and under the 1940 Act relating to the Funds (File Nos. 333–171987 and 811–22524) (the ''Registration Statement''). The Trust filed an Application for an Order under Section 6(c) of the 1940 Act for exemptions from various provisions of the 1940 Act and rules thereunder (File No. 812–14116), dated July 18, 2013 (''Exemptive Application''). The Shares will not be listed on the Exchange until an order (''Exemptive Order'') under the 1940 Act has been issued by the Commission with respect to the Exemptive Application. Investments made by the Funds will comply with the conditions set forth in the Exemptive Order. The description of the operation of the Trust and the Funds herein is based, in part, on the Registration Statement and the Exemptive Application.

[12] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel will be subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violations, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[13] For purposes of this filing, ETFs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); and Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600). All ETFs will be listed and traded on a U.S. national securities exchange. The Funds will invest in the securities of ETFs registered under the 1940 Act consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation or order of the Commission or interpretation thereof.

[14] The terms ''normally'' and ''under normal market conditions'' include, but are not limited to, the absence of extreme volatility or trading halts in the equity markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[15] According to the Registration Statement, with respect to each of the Funds, selling securities short will allow a Fund to more fully exploit insights into securities that a Fund's portfolio managers expect to underperform. Short sales generally involve the sale of a security that a Fund does not own in hopes of purchasing the same security at a later date at a lower price. To make delivery to the buyer, a Fund may borrow the security. If so, a Fund is obligated to return the security to the lender, which is accomplished by a later purchase of the security by a Fund.

more specific indexes as well, including those relating to particular sectors, markets, regions or industries.

The Fund will use a variety of proprietary and non-proprietary [sic] analytical methodologies including ''bottom-up'' fundamental analysis, macro-economic data, technical analysis, and quantitative analysis to determine the ratio of long to short positions. It also will use these tools to determine whether a particular stock or group of stocks is under-valued or over-valued and, therefore, whether to purchase or sell those securities. In reviewing companies, the Fund will apply the characteristics identified above on a case-by-case basis as the order of importance varies depending on the type of business or industry and the company being reviewed.

The ActiveShares℠ Mid-Cap Fund

According to the Registration Statement, the Fund's investment objective will be long-term capital appreciation. The Fund will seek to achieve its objective by taking long and possibly short positions in equity securities or groups of equities that the Fund's portfolio managers believe will provide long term capital appreciation. The Fund will invest primarily in securities included in the Russell 3000 Index and ETFs that primarily invest in stocks in the Russell 3000 Index.

The Fund will target an overall net equity market exposure of between 70% to 130%. However, at times the Fund's portfolio managers may reduce market exposure to less than 70%.

The Fund will purchase securities that the portfolio managers believe are undervalued and sell short securities that the portfolio managers believe are overvalued. Under normal market conditions, the Fund's net long equity market exposure will not exceed 130% and its net short equity market exposure will not exceed 30%; however, the portfolio managers may at times exceed these percentages. The Fund may hold a substantial portion of its total assets in cash or cash equivalents when it holds significant short positions.

The Fund may use ETFs to manage the Fund's overall equity market and sector exposures. In particular, the Fund's portfolio managers may take long and short positions in ETFs to increase/decrease equity market/sector exposures in place of using individual equity securities. The ETFs in which the Fund will invest are registered investment companies that seek to track the performance of an underlying index. These underlying indexes include not only broad-based market indexes but more specific indexes as well, including those relating to particular sectors, markets, regions or industries.

The Fund will use a variety of proprietary and non-propriety [sic] analytical methodologies including ''bottom-up'' fundamental analysis, macro-economic data, technical analysis, and quantitative analysis to determine the ratio of long to short positions. It also will use these tools to determine whether a particular stock or group of stocks is under-valued or over-valued and, therefore, whether to purchase or sell those securities. In reviewing companies, the Fund will apply the characteristics identified above on a case-by-case basis as the order of importance varies depending on the type of business or industry and the company being reviewed.

Other Investments

While each Fund, under normal market conditions, will invest primarily in stocks included in the Russell 3000 Index and ETFs, as described above, each Fund may invest its remaining assets in other securities and financial instruments, as described below.

According to the Registration Statement, each Fund may enter into repurchase agreements. A repurchase agreement is an instrument under which the purchaser (i.e., a Fund) acquires the security and the seller agrees, at the time of the sale, to repurchase the security at a mutually agreed upon time and price, thereby determining the yield during the purchaser's holding period. Repurchase agreements may be construed to be collateralized loans by the purchaser to the seller secured by the securities transferred to the purchaser.

Each Fund may enter into reverse repurchase agreements, which involve the sale of securities with an agreement to repurchase the securities at an agreed-upon price, date and interest payment and have the characteristics of borrowing. Generally the effect of such transactions is that the Fund can recover all or most of the cash invested in the portfolio securities involved during the term of the reverse repurchase agreement, while in many cases the Fund is able to keep some of the interest income associated with those securities.

Each Fund may invest a portion of its assets in high-quality money market instruments on an ongoing basis rather than in other investments, when it would be more efficient or less expensive for the Fund to do so, or as cover for other financial instruments held by a Fund, for liquidity purposes, or to earn interest. Money market instruments in which a Fund may invest include: (1) Short-term obligations issued by the U.S. government; (2) negotiable certificates of deposit (''CDs''), fixed time deposits and bankers' acceptances of U.S. and foreign banks and similar institutions; (3) commercial paper rated at the date of purchase ''Prime-1'' by Moody's Investors Service, Inc. or ''A–1+'' or ''A–1'' by Standard & Poor's Ratings Group, Inc., a division of The McGraw-Hill Companies, Inc., or, if unrated, of comparable quality as determined by the Adviser; [16] and (4) money market mutual funds.

Each Fund may invest in the securities of other investment companies (including money market funds) to the extent allowed by law.

Investment Restrictions

A Fund may not, with respect to 75% of its total assets, purchase securities of any issuer (except securities issued or guaranteed by the U.S. government, its agencies or instrumentalities or shares of investment companies) if, as a result, more than 5% of its total assets would be invested in the securities of such issuer; or (ii) acquire more than 10% of the outstanding voting securities of any one issuer (and for purposes of this policy, the issuer of the underlying security will be deemed to be the issuer of any respective depositary receipt.) [17]

A Fund may not invest 25% or more of its total assets in the securities of one or more issuers conducting their principal business activities in the same industry or group of industries. This limitation does not apply to investments in securities issued or guaranteed by the U.S. government, its agencies or instrumentalities, or shares of investment companies. A Fund will not invest 25% or more of its total assets in any investment company that so concentrates.[18]

Each Fund may invest up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at

[16] In determining whether a security is of ''comparable quality,'' the Adviser will consider, for example, whether the issuer of the security has issued other rated securities; whether the obligations under the security are guaranteed by another entity and the rating of such guarantor (if any); whether and (if applicable) how the security is collateralized; other forms of credit enhancement (if any); the security's maturity date; liquidity features (if any); relevant cash flow(s); valuation features; other structural analysis; macroeconomic analysis; and sector or industry analysis.

[17] The diversification standard is set forth in Section 5(b)(1) of the 1940 Act.

[18] *See* Form N–1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. *See, e.g.,* Investment Company Act Release No. 9011 (October 30, 1975), 40 FR 54241 (November 21, 1975).

the time of investment),[19] consistent with Commission guidance. Each Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of a Fund's net assets are invested in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.[20]

According to the Registration Statement, each Fund will seek to qualify for treatment as a Regulated Investment Company (''RIC'') under the Internal Revenue Code.[21]

The Shares of each Fund will conform to the initial and continued listing criteria under proposed Rule 8.900. The Funds will not invest in options, futures, forwards or swaps.

Each Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. While a Fund may invest in inverse ETFs, a Fund will not invest in leveraged (*e.g.,* 2X, −2X, 3X or −3X) ETFs. The Funds will not invest in non-U.S. equity securities.

Creations and Redemptions

Placement of Purchase Orders

Each Fund will issue Shares through the Distributor on a continuous basis at NAV. The Exchange represents that the issuance of Shares will operate in a manner substantially similar to that of other ETFs and, in particular, certain fixed-income ETFs that issue shares solely for settlement in cash. However, Shares may be issued in any amount rather than only in a specified block size.

Each Fund will issue Shares only at the NAV per Share next determined after an order in proper form is received. The Trust will sell and redeem Shares on each such day and will not suspend the right of redemption or postpone the date of payment or satisfaction upon redemption for more than seven days, other than as provided by Section 22(d) of the 1940 Act (each such day, a ''Business Day'').

Shares may be purchased from a Fund by any Depository Trust Company (''DTC'') Participant for its own account or for the account of a customer. Purchase orders will not be limited to any specified size but may be in any whole share amount. Since Shares will be paid for in cash, settlement will be through the normal continuous net settlement process. The Distributor will furnish acknowledgements to those placing such orders that the orders have been accepted, but the Distributor may reject any order which is not submitted in proper form, as described in a Fund's prospectus or Statement of Additional Information (''SAI''). Purchases of Shares will be settled in cash for an amount equal to the applicable NAV per Share purchased plus applicable transaction fees, as discussed below.

The NAV of each Fund is expected to be determined once each Business Day at a time determined by the Trust's Board of Directors (''Board''), currently anticipated to be as of the close of the regular trading session on the New York Stock Exchange (''NYSE'') (ordinarily 4:00 p.m. Eastern time) (the ''Valuation Time''). Each Fund will establish a cut-off time (''Order Cut-Off Time'') for purchase orders in proper form. To initiate a purchase of Shares, a DTC participant must submit to the Distributor an irrevocable order to purchase such Shares after the most recent prior Valuation Time but not later than the Order Cut-Off Time. The Order Cut-Off Time for a Fund may be its Valuation Time, or may be prior to the Valuation Time if the Board determines that an earlier Order Cut-Off Time for purchase of Shares is necessary and is in the best interests of Fund shareholders. It is anticipated that the Funds may adopt Order Cut-Off Times prior to their Valuation Time in order to make arrangements for any securities borrowing transactions consistent with a Fund's investment strategy that may be necessary in light of creation of Shares and in a manner consistent with orderly portfolio management. An early Order Cut-Off Time will allow the Adviser to net creations and redemptions and facilitate borrowing securities in an efficient manner.

Transaction Fees

The Trust may impose purchase or redemption transaction fees (''Transaction Fees'') in connection with the purchase or redemption of Shares from the Funds. The exact amounts of any such Transaction Fees will be determined by the Adviser but will not exceed 2%. The purpose of the Transaction Fees is to protect the continuing shareholders against possible dilutive transactional expenses, including operational processing and brokerage costs, associated with establishing and liquidating portfolio positions, including short positions, in connection with the purchase and redemption of Shares. The Adviser believes that imposing Transaction Fees will best respond to market needs and help to defray certain costs that would otherwise be borne by the Trust, such as custodian transaction fees and various other Fund overhead costs and fund accounting costs.

From time to time and for such periods as the Adviser in its sole discretion may determine, the Transaction Fees for the purchase or redemption of Shares may be increased, decreased or otherwise modified. Such Transaction Fees will be limited to amounts that will have been determined by the Adviser to be appropriate and will take into account transaction and operational processing costs associated with the recent purchases and sales of the equity securities held by the Trust. In all cases, such Transaction Fees will be limited in accordance with then-existing requirements of the Commission applicable to management investment companies offering redeemable securities.

Purchases of Shares—Secondary Market

Only DTC Participants and their customers will be able to acquire Shares at NAV directly from a Fund through the Distributor. The entire required cash payment must be transferred in the manner set forth in a Fund's SAI by the specified time on the third DTC settlement day following the day it is transmitted (the ''Transmittal Date''). These investors and others will also be able to purchase Shares in secondary market transactions at prevailing market prices. Each Fund will reserve the right to reject any purchase order at any time.

[19] In reaching liquidity decisions, the Adviser may consider the following factors: the frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace in which it trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers and the mechanics of transfer).

[20] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[21] 26 U.S.C. 851.

Redemption

Beneficial Owners may sell their Shares in the secondary market. Alternatively, investors that own enough Shares to constitute a Redemption Unit (currently, 50,000 Shares) or multiples thereof may redeem those Shares through the Distributor, which will act as the Trust's agent for redemption. The size of a Redemption Unit will be subject to change. Redemption orders for Redemption Units or multiples thereof must be placed by or through an Authorized Participant. A Beneficial Owner that is an individual, a trust exclusively for the benefit of an individual or group of related family members or a tax deferred retirement plan directed by an individual would be treated as a ''Retail Owner''. Any entity other than a trust or retirement plan exclusively for the benefit of individuals would be treated as an institutional investor. Retail Investors that wish to redeem Shares in less than Redemption Unit size may redeem those Shares directly from the Fund as described below under ''Retail Redemption Facility.''

Authorized Participant Redemption

The Shares may be redeemed to a Fund in Redemption Unit size or multiples thereof as described below. Redemption orders of Redemption Units must be placed by or through an Authorized Participant (''AP Redemption Order''). Each Fund will establish an Order Cut-Off Time for redemption orders of Redemption Units in proper form. Redemption Units of the Fund will be redeemable at their NAV per Share next determined after receipt of a request for redemption by the Trust in the manner specified below before the Order Cut-Off Time. To initiate an AP Redemption Order, an Authorized Participant must submit to the Distributor an irrevocable order to redeem such Redemption Unit after the most recent prior Valuation Time but not later than the Order Cut-Off Time. The Order Cut-Off Time for a Fund may be its Valuation Time, or may be prior to the Valuation Time if the Board determines that an earlier Order Cut-Off Time for redemption of Redemption Units is necessary and is in the best interests of Fund shareholders. An earlier Order Cut-Off Time is primarily necessary because of the redemption process for the Funds. It is contemplated that Authorized Participants will instruct the trustee of its blind trust to liquidate redemption securities in market on close orders on the date of redemption so that Authorized Participants can realize redemption proceeds as close to the Fund's NAV on the redemption date as possible. In order to allow the Adviser sufficient time to identify the redemption securities, transfer the redemption basket of portfolio securities to the blind trusts and permit the trustee adequate time to process liquidation transactions in accordance with the Authorized Participant's instructions, it will likely be necessary to employ an Order Cut-Off Time prior to that time to allow such actions to take place. It is anticipated that all Funds will adopt Order Cut-Off Times for redemptions prior to their Valuation Time in order to facilitate the timely identification and notice to the trustee of the blind trusts (as described below) of securities to be redeemed in-kind.

Consistent with the provisions of Section 22(e) of the 1940 Act and Rule 22e-2 thereunder, the right to redeem will not be suspended, nor payment upon redemption delayed, except for: (1) Any period during which the NYSE is closed other than customary weekend and holiday closings, (2) any period during which trading on the NYSE is restricted, (3) any period during which an emergency exists as a result of which disposal by a Fund of securities owned by it is not reasonably practicable or it is not reasonably practicable for a Fund to determine its NAV, and (4) for such other periods as the Commission may by order permit for the protection of shareholders.

Redemptions other than Retail Redemptions will occur primarily in-kind, although redemption payments may also be made partly or wholly in cash.[22] The Participant Agreement signed by each Authorized Participant will require establishment of a blind trust to receive distributions of securities in-kind upon redemption.[23] Each Authorized Participant will be required to appoint the Custodian as trustee of its blind trust in order to facilitate orderly processing of redemptions. While the Fund will generally distribute securities in-kind, the Adviser may determine from time to time that it is not in the Fund's best interests to distribute securities in-kind, but rather to sell securities and/or distribute cash. For example, the Adviser may distribute cash to facilitate orderly portfolio management in connection with rebalancing or transitioning a portfolio in line with its investment objective, or if there is substantially more creation than redemption activity during the period immediately preceding a redemption request, or as necessary or appropriate in accordance with applicable laws and regulations. In this manner, the Fund can use in-kind redemptions to reduce the unrealized capital gains that may, at times, exist in a Fund by distributing low cost lots of each security that a Fund needs to dispose of to maintain its desired portfolio exposures. Shareholders of a Fund would benefit from the in-kind redemptions through the reduction of the unrealized capital gains in a Fund that would otherwise have to be realized and, eventually, distributed to shareholders.

The redemption basket will consist of the same securities for all Authorized Participants on any given day subject to the Adviser's ability to make minor adjustments to address odd lots, fractional shares, tradeable sizes or other situations.

After receipt of an AP Redemption Order, the Custodian will typically deliver securities to the blind trust (which securities are determined by the Adviser) with a value approximately equal to the value of the Shares[24] tendered for redemption at the Cut-Off time. The Custodian will make delivery of the securities by appropriate entries on its books and records transferring ownership of the securities to the blind trust, subject to delivery of the Shares redeemed. The trustee of the blind trust will in turn liquidate, hedge or otherwise manage the securities based on instructions from the Authorized Participant.[25] If the trustee is instructed

[22] It is anticipated that any portion of a Fund's NAV attributable to appreciated short positions will be paid in cash, as securities sold short are not susceptible to in-kind settlement. The value of other positions not susceptible to in-kind settlement may also be paid in cash.

[23] The terms of each blind trust will be set forth as an exhibit to the applicable Participant Agreement, which will be signed by each Authorized Participant. The terms of the blind trust will provide that the trust be formed under either New York or Massachusetts State law; the Custodian will act as trustee of the blind trusts; and the trustee will be paid by the Authorized Participant a fee negotiated by the Adviser on behalf of Authorized Participants.

[24] If the NAV of the Shares redeemed differs from the value of the securities delivered to the applicable blind trust, the Fund or the blind trust will pay a cash balancing amount to compensate for the difference between the value of the securities delivered and the NAV.

[25] Because an Authorized Participant would not know the holdings of its blind trust, it is anticipated that such instructions would be generic standing instructions to the trustee. Although an Authorized Participant could, in its sole discretion, provide different standing instructions, it is expected that, in order to realize proceeds from a redemption at a value as close as possible to the redemption's NAV, all Authorized Participants will likely instruct the trustee of the blind trust to sell all securities received in kind as redemption proceeds at the close of the market on the date of redemption. For this reason, an Order Cut-Off Time for redemptions will be necessary so that the Adviser is able to identify securities to be redeemed in-kind

to sell all securities received at the close on the redemption date, the trustee will pay the liquidation proceeds net of expenses plus or minus any cash balancing amount to the Authorized Participant through DTC.[26] The redemption securities that the blind trust receives may mirror the portfolio holdings of a Fund pro rata or, if the Adviser determines to reduce one or more portfolio exposures through an in-kind distribution, may constitute only a portion of the holdings that would not be proportionate to the overall portfolio holdings of a Fund. To the extent a Fund distributes portfolio securities through an in-kind distribution to more than one blind trust for the benefit of that trust's Authorized Participant, each Fund expects to distribute a pro rata portion of the portfolio securities selected for distribution to each redeeming Authorized Participant.

The Adviser would be free to select redemption securities that do not represent an exact slice of a Fund's portfolio on any given day, so long as each Authorized Participant redeeming on a given day receives the same set of redemption securities on such day. Authorized Participants will advise the Fund of any securities they are restricted from receiving. If the Authorized Participant would receive a security that it is restricted from receiving, the Fund will deliver cash equal to the value of that security.

The Adviser might choose to select redemption securities that do not represent an exact slice of a Fund's portfolio in order to effectively implement changes to a Fund's portfolio composition, take advantage of tax strategies or address corporate actions. The Adviser represents that this freedom will benefit Beneficial Owners because the Adviser can use redemption events to liquidate unwanted positions without incurring brokerage charges or taxable gains. To address odd lots, fractional shares, tradeable sizes or other situations where dividing securities is not practical or possible, the Adviser may make minor adjustments to the pro rata portion of portfolio securities selected for distribution to each redeeming Authorized Participant on such Business Day.

The Trust will accept an AP Redemption Order in proper form. An AP Redemption Order is subject to acceptance by the Trust and must be preceded or accompanied by an irrevocable commitment to deliver the requisite number of Shares. At the time of settlement, an Authorized Participant will initiate a delivery of the Shares versus subsequent payment against the proceeds, if any, of the sale of portfolio securities distributed to the applicable blind trust plus or minus any cash balancing amounts, and less the expenses of liquidation. The Trust, on behalf of a Fund, will maintain a security interest in the assets of a blind trust and, under applicable documentation, will be entitled to such assets in the event an Authorized Participant fails to make timely delivery of redeemed Shares.

Retail Redemption Facility

Retail Investors may submit orders to redeem Shares at NAV directly with a Fund as described below (''Retail Redemption Facility''). Retail Investors will be able to place orders to redeem Shares in less than Redemption Unit size by instructing their broker to submit an order to redeem Shares directly from the Fund (''Retail Redemption Order''). The Retail Redemption Order will be submitted to the ''Redemption Agent'' by the Retail Investor's broker if the broker is a DTC Participant or by its clearing firm if it is not a DTC Participant. Redemption proceeds in connection with any Retail Redemption Order will be distributed in cash. Retail Investors may decide to redeem their Shares for cash if they want to make sure they receive the NAV and do not want to risk selling their Shares in the secondary market at a discount. Investors that are not Retail Investors can only redeem with the Fund in Redemption Unit size or larger.

On each Business Day, a Fund will process all Retail Redemption Orders received at the NAV of the Fund next calculated following submission of the Retail Redemption Order in proper form. The date the Retail Redemption Order is received in proper form will be the redemption date with respect to those Shares (the ''Redemption Date''). Each Fund will establish a cut-off time for Retail Redemption Orders in proper form, which may be earlier than the time of calculation of the NAV in order to facilitate the timely submission of such orders to the Redemption Agent for processing the order at NAV on each applicable Redemption Date. All instructions from Retail Investors to their broker to submit a Retail Redemption Order in proper form will be processed by the Redemption Agent and submitted through DTC as long as it is received prior to the cut-off time, resulting in an aggregated redemption order received by the Transfer Agent from DTC on that Business Day. Any redemption instructions submitted by a DTC Participant on behalf of Retail Investors and received in proper form by the Transfer Agent/Redemption Agent shall be irrevocable. Only Retail Redemption Orders for an amount of Shares smaller than a Redemption Unit will be considered in proper form.

The date of payment upon redemption will not exceed seven days after the Redemption Date, other than as provided by Section 22(d) of the 1940 Act. The cash proceeds from any Retail Redemption Order received are generally expected to be delivered through DTC to the applicable DTC Participant's account at DTC. The DTC Participant will in turn deposit the proceeds in the Beneficial Owner's account or the account of the financial institution carrying the account of the Beneficial Owner.

Net Asset Value

The NAV per Share of a Fund will be computed by dividing the value of the net assets of a Fund (i.e., the value of its total assets less total liabilities) by the total number of Shares of a Fund outstanding, rounded to the nearest cent. Expenses and fees, including, without limitation, the management, administration and distribution fees, will be accrued daily and taken into account for purposes of determining NAV. Interest and investment income on the Trust's assets accrue daily and will be included in the Fund's total assets. The NAV per Share for a Fund will be calculated by the Administrator and determined as of the close of the regular trading session on the New York Stock Exchange (''NYSE'') (ordinarily 4:00 p.m., E.T.) on each day that the NYSE is open. The NAV that is published will be rounded to the nearest cent; however, for purposes of determining the price of Shares in creations and redemption, the NAV will be calculated to five decimal places. The Shares of the Funds will not be priced on days on which the NYSE is closed for trading.

Shares of exchange-listed equity securities will be valued at market value, which will generally be determined using the last reported official closing or last trading price on the exchange or market on which the securities are primarily traded at the

to the Custodian prior to the close of the market on the redemption date.

[26] Under applicable provisions of the Internal Revenue Code, the Authorized Participant is expected to be deemed a ''substantial owner'' of the blind trust because it receives distributions from the blind trust. As a result, all income, gain or loss realized by the blind trust will be directly attributed to the Authorized Participant. In a redemption, the Authorized Participant will have a basis in the distributed securities equal to the fair market value at the time of the distribution and any gain or loss realized on the sale of those Shares will be taxable income to the Authorized Participant.

time of valuation. Repurchase and reverse repurchase agreements will be valued based on price quotations or other equivalent indications of value provided by a third-party pricing service. Money market instruments (as described above) will be valued based on price quotations or other equivalent indications of value provided by a third-party pricing service.

When last sale prices and market quotations are not readily available, are deemed unreliable or do not reflect material events occurring between the close of local markets and the time of valuation, investments will be valued using fair value pricing as determined in good faith by the Adviser under procedures established by and under the general supervision and responsibility of the Trust's Board of Trustees. Investments that may be valued using fair value pricing include, but are not limited to: (1) Securities that are not actively traded; (2) securities of an issuer that becomes bankrupt or enters into a restructuring; and (3) securities whose trading has been halted or suspended.

The frequency with which each Fund's investments will be valued using fair value pricing will primarily be a function of the types of securities and other assets in which the respective Fund will invest pursuant to its investment objective, strategies and limitations. If the Funds invest in open-end management investment companies registered under the 1940 Act (other than ETFs), they may rely on the NAVs of those companies to value the shares they hold of them. Those companies may also use fair value pricing under some circumstances.

Valuing the Funds' investments using fair value pricing involves the consideration of a number of subjective factors and thus the prices for those investments may differ from current market valuations. Accordingly, fair value pricing could result in a difference between the prices used to calculate NAV and the prices used to determine a Fund's Portfolio Indicative Value (''PIV''), as described below, which could result in the market prices for Shares deviating from NAV.

Availability of Information

The Funds' Web site (*www.precidianfunds.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for each Fund that may be downloaded. The Funds' Web site will include additional quantitative information updated on a daily basis, including, for each Fund, (1) daily trading volume, the prior Business Day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''),[27] and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters.

As noted above, a mutual fund is required to file with the Commission its complete portfolio schedules for the second and fourth fiscal quarters on Form N–SAR under the 1940 Act, and is required to file its complete portfolio schedules for the first and third fiscal quarters on Form N–Q under the 1940 Act, within 60 days of the end of the quarter. Form N–Q requires funds to file the same schedules of investments that are required in annual and semi-annual reports to shareholders. The Trust's SAI and each Fund's shareholder reports will be available free upon request from the Trust. These documents and forms may be viewed on-screen or downloaded from the Commission's Web site at *www.sec.gov.*

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Updated price information for the securities included in the Russell 1000, Russell 2000 and Russell 3000 Indexes, and for other U.S. exchange-listed equity securities is available through major market data vendors or securities exchanges trading such securities. Information relating to Russell 1000, Russell 2000 and Russell 3000 Index components is available at *www.russell.com.* The intraday, closing and settlement prices of money market instruments (as described above), repurchase agreements and reverse repurchase agreements will be readily available from published or other public sources, or major market data vendors such as Bloomberg and Thomson Reuters. The NAV of any investment company security investment will be readily available on the Web site of the relevant investment company and from major market data vendors. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the Portfolio Indicative Value (''PIV''), as defined in NYSE Arca Equities Rule 8.900(c)(3) and as described further below, will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session.

Dissemination of the Portfolio Indicative Value

The PIV, which is approximate [sic] value of each Fund's investments on a per Share basis, will be disseminated every 15 seconds during the Exchange's Core Trading Session. The PIV should not be viewed as a ''real-time'' update of NAV because the PIV may not be calculated in the same manner as NAV, which is computed once per day.

An independent third party calculator will calculate the PIV for each Fund during the Exchange's Core Trading Session by dividing the ''Estimated Fund Value'' (as described below) as of the time of the calculation by the total number of outstanding Shares of that Fund. ''Estimated Fund Value'' is the sum of the estimated amount of cash held in a Fund's portfolio, the estimated amount of accrued interest owed to a Fund and the estimated value of the securities held in the Fund's portfolio, minus the estimated amount of a Fund's liabilities.

The Funds will provide the independent third party calculator with information to calculate the PIV, but the Funds will not be involved in the actual calculation of the PIV.[28]

Additional information regarding the Trust and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes will be included in the Registration Statement. All terms relating to the Funds that are referred to, but not defined in, this proposed rule change are defined in the Registration Statement.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Funds.[29] Trading in Shares of the

[27] The Bid/Ask Price of a Fund will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of a Fund's NAV. The records relating to Bid/Ask Prices will be retained by each Fund and its service providers.

[28] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available PIVs published on CTA or other data feeds. Dissemination of the PIV will allow investors to determine the value of the underlying portfolio of a Fund throughout the trading day.

[29] *See* NYSE Arca Equities Rule 7.12.

Funds will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) If the PIV applicable to a Fund's Shares is not being disseminated as required; (2) the extent to which trading is not occurring in the securities and/or the financial instruments comprising the holdings of a Fund; or (3) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.900(d)(2)(C), which sets forth circumstances under which Shares of the Funds may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m., E.T. in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, Commentary .03, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.900. The Exchange represents that, for initial and/or continued listing, each Fund will be in compliance with Rule 10A–3 under the Act,[30] as provided by NYSE Arca Equities Rule 5.3. A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares of each Fund that the NAV per Share of each Fund will be calculated daily and will be made available to all market participants at the same time.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[31] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares, underlying stocks and ETFs with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and FINRA, on behalf of the Exchange, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, underlying stocks and ETFs from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[32]

The Funds' Adviser will make available to FINRA and the Exchange the portfolio holdings of each Fund in order to facilitate the performance of the surveillances referred to above.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares and the differing rights of Retail Investors and others to redeem shares; (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated PIV will not be calculated or publicly disseminated; (4) how information regarding the PIV is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Funds are subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4:00 p.m., E.T. each trading day.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[33] in general, and furthers the objectives of Section 6(b)(5) of the Act,[34] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that proposed Rule 8.900 is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading of Managed Portfolio Shares provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 8.900(d) sets forth initial and continued listing criteria applicable to Managed Portfolio Shares. Proposed Rule 8.900(d)(1) provides that, for each series of Managed Portfolio Shares, the Corporation will establish a minimum number of Managed Portfolio Shares required to be outstanding at the time of commencement of trading. In addition, the Corporation will obtain a representation from the issuer of each series of Managed Portfolio Shares that the NAV per share for the series will be calculated daily and that the NAV will be made available to all market participants at the same time. Proposed Rule 8.900(d)(2) provides that each

[30] *See* 17 CFR 240.10A–3.

[31] FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[32] For a list of the current members of ISG, see *www.isgportal.org.*

[33] 15 U.S.C. 78f(b).

[34] 15 U.S.C. 78f(b)(5).

series of Managed Portfolio Shares will be listed and traded subject to application of the specified continued listing criteria, as described above. Proposed Rule 8.900(d)(2)(A) provides that the PIV for Managed Portfolio Shares will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Core Trading Session. Proposed Rule 8.900(d)(2)(C) provides that, if the PIV of a series of Managed Portfolio Shares is not being disseminated as required, the Corporation may halt trading during the day in which the interruption to the dissemination of the PIV occurs. If the interruption to the dissemination of the PIV persists past the trading day in which it occurred, the Corporation will halt trading no later than the beginning of the trading day following the interruption. If a series of Managed Portfolio Shares is trading on the Corporation pursuant to UTP, the Corporation will halt trading in that series as specified in Rule 7.34(a). In addition, if the Exchange becomes aware that the NAV with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time, it will halt trading in such securities until such time as the NAV is available to all market participants. Proposed Commentary .05 to NYSE Arca Equities Rule 8.900 provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio. Personnel who make decisions on the Investment Company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Investment Company portfolio.

With respect to the proposed listing and trading of Shares of the Funds, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.900. Price information for the exchange-listed equity securities held by the Funds will be available through major market data vendors or securities exchanges listing and trading such securities. All exchange-listed equity securities held by the Funds will be listed on national securities exchanges. The listing and trading of such securities is subject to rules of the exchanges on which they are listed and traded, as approved by the Commission. The Funds will primarily hold securities in the Russell 3000 Index or ETFs that invest primarily in the Russell 3000 Index. Further, the Funds will not invest in options, futures or swaps. A Fund's investments will be consistent with its respective investment objective and will not be used to enhance leverage. The Funds will not invest in non-U.S. issues. FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and underlying stocks and ETFs with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, underlying stocks and ETFs from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

The Exchange, after consulting with various Lead Market Makers that trade ETFs on the Exchange, believes that market makers will be able to make efficient and liquid markets priced near the PIV as long as an accurate PIV is disseminated every 15 seconds and market makers have knowledge of a fund's means of achieving its investment objective, even without daily disclosure of a fund's underlying portfolio. The Exchange believes that market makers will employ risk-management techniques such as ''statistical arbitrage'', which is currently used throughout the financial services industry, to make efficient markets in exchange traded products.[35] This ability should permit market makers to make efficient markets in Fund Shares without knowledge of a fund's underlying portfolio.

The Exchange understands that traders use statistical analysis to derive correlations between different sets of instruments to identify opportunities to buy or sell one set of instruments when it is mispriced relative to the others. For Managed Portfolio Shares, market makers will initially use the knowledge of a fund's means of achieving its investment objective, as described in the applicable fund registration statement, to construct a hedging proxy for a fund to manage a market maker's quoting risk in connection with trading fund shares. Market makers will then conduct statistical arbitrage between their hedging proxy (for example, the Russell 1000 Index) and shares of a fund, buying and selling one against the other over the course of the trading day. Eventually, at the end of each day, they will evaluate how their proxy performed in comparison to the price of a fund's shares, and use that analysis as well as knowledge of risk metrics, such as volatility and turnover, to enhance their proxy calculation to make it a more efficient hedge.

Market makers have indicated to the Exchange that, after the first few days of trading, there will be sufficient data to run a statistical analysis which will lead to spreads being tightened substantially around PIV. This is similar to certain other existing exchange traded products (for example, ETFs that invest in foreign securities that do not trade during U.S. trading hours), in which spreads may be generally wider in the early days of trading and then narrow as market makers gain more confidence in their real-time hedges.

The Lead Market Makers also indicated that, as with some other new exchange-traded products, spreads may be generally wider in the early days of trading and would tend to narrow as market makers gain more confidence in the accuracy of their hedges and their ability to adjust these hedges in real-time relative to the published PIV and gain an understanding of the applicable market risk metrics such as volatility and turnover, and as natural buyers and sellers enter the market. Other relevant factors cited by Lead Market Makers were that a fund's investment objectives are clearly disclosed in the applicable prospectus, the existence of quarterly portfolio disclosure, and the ability to create shares in any size.

The Commission's concept release regarding ''Actively Managed Exchange-Traded Funds'' highlighted several issues that could impact the Commission's willingness to authorize the operation of an actively-managed ETF, including whether effective arbitrage of the ETF shares exists.[36] The Concept Release identifies the transparency of a fund's portfolio and the liquidity of the securities in a fund's portfolio as central to effective arbitrage. However, certain existing ETFs with portfolios of foreign securities have shown their ability to trade efficiently in the secondary market at approximately their NAV even though they do not provide opportunities for riskless

[35] *See* note 10, *supra.*

[36] *See* Investment Company Act Release No. 25258 (November 8, 2001) (the ''Concept Release'').

arbitrage transactions during much of the trading day.[37] Such ETFs have been shown to have pricing characteristics very similar to ETFs that can be arbitraged in this manner. For example, index-based ETFs containing securities that trade during different trading hours than the ETF, such as ETFs that hold Asian stocks, have demonstrated efficient pricing characteristics notwithstanding the inability of market professionals to engage in ''riskless arbitrage'' with respect to the underlying portfolio for most, or even all, of the U.S. trading day when Asian markets are closed. Pricing for shares of such ETFs is efficient because market professionals are still able to hedge their positions with offsetting, correlated positions in derivative instruments during the entire trading day.

The real-time dissemination of a fund's PIV, together with the right of Authorized Participants to create and redeem each day at the NAV, will be sufficient for market participants to value and trade shares in a manner that will not lead to significant deviations between the shares' Bid/Ask Price and NAV. In addition, with respect to Shares of the Funds, the Retail Redemption Facility will permit retail shareholders holding amounts smaller than a Redemption Unit to redeem at NAV on any day the Exchange is open in the event there is any negative variance between the NAV of a Fund's Shares and the secondary market price of Shares at the Valuation Time.

The pricing efficiency with respect to trading a series of Managed Portfolio Shares will not generally rest on the ability of market participants to arbitrage between the shares and a fund's portfolio, but rather on the ability of market participants to assess a fund's underlying value accurately enough throughout the trading day in order to hedge positions in shares effectively. Professional traders will buy shares that they perceive to be trading at a price less than that which will be available at a subsequent time, and sell shares they perceive to be trading at a price higher than that which will be available at a subsequent time. It is expected that, as part of their normal day-to-day trading activity, market makers assigned to shares by the Exchange, off-exchange market makers, firms that specialize in electronic trading, hedge funds and other professionals specializing in short-term, non-fundamental trading strategies will assume the risk of being ''long'' or ''short'' shares through such trading and will hedge such risk wholly or partly by simultaneously taking positions in correlated assets[38] or by netting the exposure against other, offsetting trading positions—much as such firms do with existing ETFs and other equities. Disclosure of a fund's investment objective and principal investment strategies in its prospectus and SAI, along with the dissemination of the PIV every 15 seconds, should permit professional investors to engage easily in this type of hedging activity.[39]

With respect to trading of Shares of the Funds, the ability of market participants to buy and sell Shares at prices near the PIV is dependent upon their assessment that the PIV is a reliable, indicative real-time value for a Fund's underlying holdings. Market participants are expected to accept the PIV as a reliable, indicative real-time value because (1) the PIV will be calculated and disseminated based on a Fund's actual portfolio holdings (rather than a proxy portfolio), (2) the securities in which the Funds plan to invest are generally highly liquid and actively traded and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the PIV at or near the close of trading is indeed predictive of the actual NAV. Because there is less risk of variability between the current PIV and the NAV nearer to the Valuation Time, it is expected that the bid/ask spread for Shares will initially tend to be less as the market approaches the close and market participants have a very high degree of certainty that they can trade at a level that reflects the current value of a Fund's holdings. It is also expected, however, that market participants will quickly be able to determine, after gaining experience with how various market factors (*e.g.,* general market movements, sensitivity or correlations of the PIV to intraday movements in interest rates or commodity prices, other benchmarks, etc.) affect PIV, how best to hedge long or short positions taken in Shares in a manner that will permit them to provide a Bid/Ask Price for Shares that is near to the PIV throughout the day. The ability of market participants to accurately hedge their positions should serve to minimize any divergence between the secondary market price of the Shares and the PIV, as well as create liquidity in the Shares.

The real-time dissemination of a Fund's PIV, together with the ability of Authorized Participants to create and redeem each day at the NAV, will be crucial for market participants to value and trade Shares in a manner that will not lead to significant deviations between the Shares' Bid/Ask Price and NAV.[40] In addition, the Retail Redemption Facility will permit retail shareholders holding amounts smaller than a Redemption Unit to redeem at NAV on any day the Exchange is open in the event there is any negative variance between NAV of a Fund's

[37] The Adviser represents that the mechanics of arbitrage and hedging differ. Prior Rule 10a–1 and Regulation T under the Act both describe arbitrage as either buying and selling the same security in two different markets or buying and selling two different securities, one of which is convertible into the other. This is also known as a ''riskless arbitrage'' transaction in that the transaction is risk free since it generally consists of buying an asset at one price and simultaneously selling that same asset at a higher price, thereby generating a profit on the difference. Hedging, on the other hand, involves managing risk by purchasing or selling a security or instrument that will track or offset the value of another security or instrument. Arbitrage and hedging are both used to manage risk; however, they involve different trading strategies.

[38] Price correlation trading is used throughout the financial industry. It is used to discover both trading opportunities to be exploited, such as currency pairs and statistical arbitrage, as well as for risk mitigation such as dispersion trading and beta hedging. These correlations are a function of differentials, over time, between one or multiple securities pricing. Once the nature of these price deviations have been quantified, a universe of securities is searched in an effort to, in the case of a hedging strategy, minimize the differential. Once a suitable hedging basket has been identified, a trader can minimize portfolio risk by executing the hedging basket. The trader then can monitor the performance of this hedge throughout the trade period, making corrections where warranted.

[39] With respect to trading in Shares of the Funds, market participants manage risk in a variety of ways. It is expected that market participants will be able to determine how to trade Shares at levels approximating the PIV without taking undue risk by gaining experience with how various market factors (*e.g.,* general market movements, sensitivity of the PIV to intraday movements in interest rates or commodity prices, etc.) affect PIV, and by finding hedges for their long or short positions in Shares using instruments correlated with such factors. The Adviser expects that market participants will initially determine the PIV's correlation to a major large capitalization equity benchmark with active derivative contracts, such as the Russell 1000 Index, and the degree of sensitivity of the PIV to changes in that benchmark. For example, using hypothetical numbers for illustrative purposes, market participants should be able to determine quickly that price movements in the Russell 1000 Index predict movements in a Fund's PIV 95% of the time (an acceptably high correlation) but that the PIV generally moves approximately half as much as the Russell 1000 Index with each price movement. This information is sufficient for market participants to construct a reasonable hedge—buy or sell an amount of futures, swaps or ETFs that track the Russell 1000 equal to half the opposite exposure taken with respect to Shares. Market participants will also continuously compare the intraday performance of their hedge to a Fund's PIV. If the intraday performance of the hedge is correlated with the PIV to the expected degree, market participants will feel comfortable they are appropriately hedged and can rely on the PIV as appropriately indicative of a Fund's performance.

[40] The statements in the Statutory Basis section of this filing relating to pricing efficiency, arbitrage, and activities of market participants, including market makers and Authorized Participants, are based on representations by the Adviser and review by the Exchange.

Shares and the secondary market price of Shares at the Valuation Time.

In a typical index-based ETF, it is necessary for Authorized Participants to know what securities must be delivered in a creation or will be received in a redemption. For Managed Portfolio Shares, however, Authorized Participants do not need to know the securities comprising the portfolio of a Fund since creations are for cash and redemptions are handled through the blind trust mechanism. The use of cash for creations, and in-kind redemption through a blind trust, will preserve the integrity of the active investment strategy and eliminate the potential for ''free riding'', while still providing investors with the advantages of the ETF structure.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of an issue of Managed Portfolio Shares that the NAV per share of a fund will be calculated daily and that the NAV and will be made available to all market participants at the same time. Investors can also obtain a fund's SAI, shareholder reports, and its Form N–CSR and Form N–SAR. A fund's SAI and shareholder reports will be available free upon request from the applicable fund, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's Web site. In addition, with respect to the Funds, a large amount of information will be publicly available regarding the Funds and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line. Information regarding the intra-day value of the Shares of the Fund, which is the PIV as defined in proposed NYSE Arca Equities Rule 8.900(c)(3), will be widely disseminated every 15 seconds throughout the Exchange's Core Trading Session by one or more major market data vendors. The Web site for the Funds will include a form of the prospectus for the Funds that may be downloaded, and additional data relating to NAV and other applicable quantitative information, updated on a daily basis. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to NYSE Arca Equities Rule 8.900(d)(2)(C), which sets forth circumstances under which Shares of the Funds may be halted. In addition, as noted above, investors will have ready access to the PIV, and quotation and last sale information for the Shares. The Shares will conform to the initial and continued listing criteria under proposed Rule 8.900. The Funds will not invest in options, futures, forwards or swaps. Each Fund's investments will be consistent with its investment objective and will not be used to enhance leverage. While a Fund may invest in inverse ETFs, a Fund will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs. The Funds will not invest in non-U.S. equity securities.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the PIV and quotation and last sale information for the Shares.

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 believes the proposed rule change would permit listing and trading of another type of actively-managed ETF that has characteristics different from existing actively-managed and index ETFs, and would introduce additional competition among various ETF products to the benefit of investors.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days after publication (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number *SR–NYSEArca–2014–10* on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2014–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of

10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2014–10 and should be submitted on or before March 19, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[41]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–04130 Filed 2–25–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–71586; File No. SR–Topaz-2014–06]

Self-Regulatory Organizations; Topaz Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Amendment of Topaz Exchange, LLC's Constitution, Certificate of Formation, Limited Liability Company Agreement, Rules and Schedule of Fees To Change the Name of the Exchange to ISE Gemini, LLC

February 20, 2014.

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 February 10, 2014, Topaz Exchange, LLC (the ''Exchange'') filed with the Securities and Exchange Commission (the ''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 to amend its Constitution, Certificate of Formation, LLC Agreement, Rules and Schedule of Fees to change the name of the Exchange to ISE Gemini, LLC. The Exchange is also proposing one other technical change to its LLC Agreement for clarification purposes. The text of the proposed rule change is available at the Commission's Public Reference Room and on the Exchange's Internet Web site at *http://www.ise.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Constitution, Certificate of Formation, LLC Agreement, Rules and Schedule of Fees, in each case, to change the name of the Exchange to ISE Gemini, LLC. The Exchange is also proposing one technical revision to the LLC Agreement to reflect that the LLC Agreement has been approved.

At the time of formation, the name of the Exchange was established as ''Topaz Exchange, LLC.'' As of the launch date, the Exchange was doing business as ''ISE Gemini.'' The Exchange has now determined that for marketing purposes, it would be desirable to change the name of the Exchange to ''ISE Gemini, LLC.''

Specifically, the Constitution and Certificate of Formation[3] would be amended to remove the reference to ''Topaz Exchange, LLC'' and replace it with ''ISE Gemini, LLC.''

In the LLC Agreement, references to ''Topaz Exchange, LLC'' and ''Topaz'' would be replaced with ''ISE Gemini, LLC'' and ''ISE Gemini,'' respectively. In addition, the following language located on the signature page of the LLC Agreement would be deleted in light of the fact that the LLC Agreement has been approved:

''To be approved at the first meeting of the Interim Board of Directors of Topaz Exchange, LLC which will be held after the grant of registration of the Topaz Form 1 application by the U.S. Securities Exchange Commission.''

In the Exchange's Rules and Schedule of Fees, references to ''Topaz Exchange, LLC'' and ''Topaz,'' would be replaced with ''ISE Gemini, LLC'' and ''ISE Gemini,'' respectively.

None of the foregoing changes are substantive.

2. Statutory Basis

The basis under the Securities Exchange Act of 1934 (the ''Exchange Act'') for this proposed rule change is the requirement under Section 6(b)(5) that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange proposes to change its name for marketing purposes, and the proposed rule change is intended to accurately reflect the name change in the Exchange's rules and governing documents. In addition, as a technical change, the Exchange is proposing to delete an outdated explanation on the signature page of the LLC Agreement to reflect the current state of affairs, which is in line with good corporate governance practices.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change to change the name of the Exchange to ISE Gemini, LLC is technical in nature, and therefore, does not implicate any burdens 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 unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of

[41] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Upon effectiveness of this rule change to change the name of the Exchange to ISE Gemini, LLC, the Exchange will officially amend its Certificate of Formation in the State of Delaware to reflect the new name, as indicated in Exhibit 5B attached hereto.

the Act[4] and Rule 19b–4(f)(3)[5] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form *http://www.sec.gov/rules/sro.shtml*; or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–Topaz–2014–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Topaz–2014–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method.

The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Topaz–2014–06 and should be submitted on or before March 19, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–04129 Filed 2–25–14; 8:45 am]

BILLING CODE 8011–01–P

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 19b–4(f)(3).

[6] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

Notice of Funding Availability for the Small Business Transportation Resource Center Program

AGENCY: Office of Small and Disadvantaged Business Utilization (OSDBU), Office of the Secretary of Transportation (OST), Department of Transportation (DOT).

ACTION: Notice of Funding Availability for the South Atlantic Region SBTRC.

SUMMARY: The Department of Transportation (DOT), Office of the Secretary (OST), Office of Small and Disadvantaged Business Utilization (OSDBU) announces the opportunity for; (1) business centered community-based organizations; (2) transportation-related trade associations; (3) colleges and universities; (4) community colleges or; (5) chambers of commerce, registered with the Internal Revenue Service as 501 C(6) or 501 C(3) tax-exempt organizations, to compete for participation in OSDBU's Small Business Transportation Resource Center (SBTRC) program in the South Atlantic Region (Kentucky, North Carolina, Virginia, West Virginia).

OSDBU will enter into Cooperative Agreements with these organizations to provide outreach to the small business community in their designated region and provide financial and technical assistance, business training programs, business assessment, management training, counseling, marketing and outreach, and the dissemination of information, to encourage and assist small businesses to become better prepared to compete for, obtain, and manage DOT funded transportation-related contracts and subcontracts at the federal, state and local levels. Throughout this notice, the term ''small business'' will refer to: 8(a), small disadvantaged businesses (SDB), disadvantaged business enterprises (DBE), women owned small businesses (WOSB), HubZone, service disabled veteran owned businesses (SDVOB), and veteran owned small businesses (VOSB). Throughout this notice, ''transportation-related'' is defined as the maintenance, rehabilitation, restructuring, improvement, or revitalization of any of the nation's modes of transportation.

Funding Opportunity Number: USDOT–OST–OSDBU–SBTRC–2014–16.

Catalog of Federal Domestic Assistance (CFDA) Number: 20.910 Assistance to small and disadvantaged businesses.

Type of Award: Cooperative Agreement Grant.

Award Ceiling: $145,000.

Award Floor: $120,000.

Program Authority: DOT is authorized under 49 U.S.C. § 332 (b) (4), (5) & (7) to design and carry out programs to assist small disadvantaged businesses in getting transportation-related contracts and subcontracts; develop support mechanisms, including management and technical services, that will enable small disadvantaged businesses to take advantage of those business opportunities; and to make arrangements to carry out the above purposes.

DATES: Complete Proposals must be electronically submitted to OSDBU via email on or before March 14, 2014 6:00 p.m. Eastern Standard Time (EST). Proposals received after the deadline will be considered non-responsive and will not be reviewed. The applicant is advised to request delivery receipt notification for email submissions. DOT plans to give notice of award for the competed region on or before March 28, 2014.

ADDRESSES: Applications must be electronically submitted to OSDBU via email at *SBTRC@dot.gov.*

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice, contact Mr. Mark Antoniewicz, Small Business Specialist, U.S. Department of Transportation, Office of Small and Disadvantaged Business Utilization, 1200 New Jersey Avenue SE. W56–462, Washington, DC, 20590. Telephone: (202) 366–1930. Email: *mark.antoniewicz@dot.gov.*

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1. Introduction

1.1 Background

The DOT established OSDBU in accordance with Public Law 95–507, an amendment to the Small Business Act and the Small Business Investment Act of 1958.

The mission of OSDBU at DOT is to ensure that the small and disadvantaged business policies and goals of the Secretary of Transportation are developed and implemented in a fair, efficient and effective manner to serve small and disadvantaged businesses throughout the country. The OSDBU also administers the provisions of Title 49, Section 332, the Minority Resource Center (MRC) which includes the duties of advocacy, outreach and financial services on behalf of small and disadvantaged business and those certified under CFR 49 parts 23 and or 26 as Disadvantaged Business Enterprises (DBE) and the development of programs to encourage, stimulate, promote and assist small businesses to become better prepared to compete for, obtain and manage transportation-related contracts and subcontracts.

The Regional Assistance Division of OSDBU, through the SBTRC program, allows OSDBU to partner with local organizations to offer a comprehensive delivery system of business training, technical assistance and dissemination of information, targeted towards small business transportation enterprises in their regions.

1.2 Program Description and Goals

The national SBTRC program utilizes Cooperative Agreements with chambers of commerce, trade associations, educational institutions and business-centered community based organizations to establish SBTRCs to provide business training, technical assistance and information to DOT grantees and recipients, prime contractors and subcontractors. In order to be effective and serve their target audience, the SBTRCs must be active in the local transportation community in order to identify and communicate opportunities and provide the required technical assistance. SBTRCs must already have, or demonstrate the ability to, establish working relationships with the state and local transportation agencies and technical assistance agencies (i.e. The U.S. Department of Commerce's Minority Business Development Centers (MBDCs), Small Business Development Centers (SBDCs), and Procurement Technical Assistance Centers (PTACs), SCORE and State DOT highway supportive services contractors in their region. Utilizing these relationships and their own expertise, the SBTRCs are involved in activities such as information dissemination, small business counseling, and technical assistance with small businesses currently doing business with public and private entities in the transportation industry.

Effective outreach is critical to the success of the SBTRC program. In order for their outreach efforts to be effective, SBTRCs must be familiar with DOT's Operating Administrations, its funding sources, and how funding is awarded to DOT grantees, recipients, contractors, subcontractors, and its financial assistance programs. SBTRCs must provide outreach to the regional small business transportation community to disseminate information and distribute DOT-published marketing materials, such as Short Term Lending Program (STLP) Information, Bonding Education Program (BEP) information, SBTRC brochures and literature, Procurement Forecasts; Contracting with DOT booklets, Women and Girls in Transportation Initiative (WITI) information, and any other materials or resources that DOT or OSDBU may develop for this purpose. To maximize outreach, the SBTRC may be called upon to participate in regional and national conferences and seminars. Quantities of DOT publications for on-hand inventory and dissemination at conferences and seminars will be available upon request from the OSDBU office.

1.3 Description of Competition

The purpose of this Request For Proposal (RFP) is to solicit proposals from transportation-related trade associations, chambers of commerce, community based entities, colleges and universities, community colleges, and any other qualifying transportation-related non-profit organizations with the desire and ability to partner with OSDBU to establish and maintain an SBTRC.

It is OSDBU's intent to award a Cooperative Agreement to one organization in the South Atlantic Region, from herein referred to as ''region'', in this solicitation. However, if warranted, OSDBU reserves the option to make multiple awards to selected partners. Proposals submitted for a region must contain a plan to service the states throughout the South Atlantic Region (Kentucky, North Carolina, Virginia, West Virginia) the entire region, not just the SBTRC's state or local geographical area.

The region's SBTRC headquarters must be established in one of the designated states set forth below. Submitted proposals must also contain justification for the establishment of the SBTRC headquarters in a particular city within the designated state.

SBTRC Region Competed in This Solicitation

South Atlantic Regions:
North Carolina
Virginia
Kentucky
West Virginia

Program requirements and selection criteria, set forth in Sections 2 and 4 respectively, indicate that the OSDBU intends for the SBTRC to be multidimensional; that is, the selected organization must have the capacity to effectively access and provide supportive services to the broad range of small businesses within the respective geographical region. To this end, the SBTRC must be able to demonstrate that they currently have established relationships within the geographic region with whom they may coordinate and establish effective networks with DOT grant recipients and local/regional technical assistance agencies to maximize resources.

Cooperative agreement awards will be distributed to the region(s) as follows:

South Atlantic Region
Ceiling: $145,000 per year
Floor: $120,000 per year

Cooperative agreement awards by region are based upon an analysis of DBEs, Certified Small Businesses, and US DOT transportation dollars in each region.

It is OSDBU's intent to maximize the benefits received by the small business transportation community through the SBTRC. Funding may be utilized to reimburse an on-site Project Director up to 100% of salary plus fringe benefits, an on-site Executive Director up to 20% of salary plus fringe benefits, up to

100% of a Project Coordinator salary plus fringe benefits, the cost of designated SBTRC space, other direct costs, and all other general and administrative expenses. Selected SBTRC partners will be expected to provide in-kind administrative support. Submitted proposals must contain an alternative funding source with which the SBTRC will fund administrative support costs. Preference will be given to proposals containing in-kind contributions for the Project Director, the Executive Director, the Project Coordinator, cost of designated SBTRC space, other direct costs, and all other general and administrative expenses.

1.4 Duration of Agreements

The cooperative agreement will be awarded for a period of 12 months (one year) with options for two (2) additional one year periods. OSDBU will notify the SBTRC of our intention to exercise an option year or not to exercise an option year 30 days in advance of expiration of the current year.

1.5 Authority

DOT is authorized under 49 U.S.C. § 332(b)(4), (5) & (7) to design and carry out programs to assist small disadvantaged businesses in getting transportation-related contracts and subcontracts; develop support mechanisms, including management and technical services, that will enable small disadvantaged businesses to take advantage of those business opportunities; and to make arrangements to carry out the above purposes.

1.6 Eligibility Requirements

To be eligible, an organization must be an established, nonprofit, community-based organization, transportation-related trade association, chamber of commerce, college or university, community college, and any other qualifying transportation-related non-profit organization which has the documented experience and capacity necessary to successfully operate and administer a coordinated delivery system that provides access for small businesses to prepare and compete for transportation-related contracts.

In addition, to be eligible, the applicant organization must:

(A) Be an established 501C(3) or 501C(6) tax-exempt organization and provide documentation as verification. No application will be accepted without proof of tax-exempt status;

(B) Have at least one year of documented and continuous experience prior to the date of application in providing advocacy, outreach, and technical assistance to small businesses within the region in which proposed services will be provided. Prior performance providing services to the transportation community is preferable, but not required; and

(C) Have an office physically located within the proposed city in the designated headquarters state in the region for which they are submitting the proposal that is readily accessible to the public.

2. Program Requirements

2.1 Recipient Responsibilities

(A) Assessments, Business Analyses

1. Conduct an assessment of small businesses in the SBTRC region to determine their training and technical assistance needs, and use information that is available at no cost to structure programs and services that will enable small businesses to become better prepared to compete for and receive transportation-related contract awards.

2. Contact other federal, state and local government agencies, such as the U.S. Small Business Administration (SBA), state and local highway agencies, state and local airport authorities, and transit authorities to identify relevant and current information that may support the assessment of the regional small business transportation community needs.

(B) General Management & Technical Training and Assistance

1. Utilize OSDBU's Intake Form to document each small business assisted by the SBTRC and type of service(s) provided. The completed form must be transmitted electronically to the SBTRC Program Analyst on a quarterly basis, accompanied by a narrative report on the activities and performance results for that period. The data gathered must be supportive by the narrative and must relate to the numerical data on the quarterly reports.

2. Ensure that an array of information is made available for distribution to the small business transportation community that is designed to inform and educate the community on DOT/OSDBU services and opportunities.

3. Coordinate efforts with OSDBU's in order to maintain an on-hand inventory of DOT/OSDBU informational materials for general dissemination and for distribution at transportation-related conferences and other events.

(C) Business Counseling

1. Collaborate with agencies, such as State, Regional, and Local Transportation Government Agencies, SBA, U.S. Department of Commerce's Minority Business Development Centers (MBDCs), Service Corps of Retired Executives (SCORE), Procurement Technical Assistance Centers (PTACs), and Small Business Development Centers (SBDCs), to offer a broad range of counseling services to transportation-related small business enterprises.

2. Create a technical assistance plan that will provide each counseled participant with the knowledge and skills necessary to improve the management of their own small business to expand their transportation-related contracts and subcontracts portfolio.

3. Provide a minimum of 20 hours of individual or group counseling sessions to small businesses per month.

(D) Planning Committee

1. Establish a Regional Planning Committee consisting of at least 7 members that includes representatives from the regional community and federal, state, and local agencies. The highway, airport, and transit authorities for the SBTRC's headquarters state must have representation on the planning committee. This committee shall be established no later than 60 days after the execution of the Cooperative agreement between the OSDBU and the selected SBRTC.

2. Provide a forum for the federal, state, and local agencies to disseminate information about upcoming procurements.

3. Hold either monthly or quarterly meetings at a time and place agreed upon by SBTRC and planning committee members.

4. Use the initial session (teleconference call) by the SBTRC explain the mission of the committee and identify roles of the staff and the members of the group.

5. Responsibility for the agenda and direction of the Planning Committee should be handled by the SBTRC Executive Director or his/her designee.

(E) Outreach Services/Conference Participation

1. Utilize the services of the System for Award Management (SAM) and other sources to construct a database of regional small businesses that currently or may in the future participate in DOT direct and DOT funded transportation related contracts, and make this database available to OSDBU, upon request.

2. Utilize the database of regional transportation-related small businesses to match opportunities identified through the planning committee forum, FedBiz Opps (a web-based system for posting solicitations and other Federal

procurement-related documents on the Internet), and other sources to eligible small businesses and inform the small business community about those opportunities.

3. Develop a ''targeted'' database of firms (100–150) that have the capacity and capabilities, and are ready, willing and able to participate in DOT contracts and subcontracts immediately. This control group will receive ample resources from the SBTRC, i.e., access to working capital, bonding assistance, business counseling, management assistance and direct referrals to DOT agencies at the state and local levels, and to prime contractors as effective subcontractor firms.

4. Identify regional, state and local conferences where a significant number of small businesses, with transportation related capabilities, are expected to be in attendance. Maintain and submit a list of those events to the SBTRC Program Analyst for review and posting on the OSDBU Web site on a monthly basis. Clearly identify the events designated for SBTRC participation and include recommendations for OSDBU participation.

5. Conduct outreach and disseminate information to small businesses at regional transportation-related conferences, seminars, and workshops. In the event that the SBTRC is requested to participate in an event, the SBTRC will send DOT materials, the OSDBU banner and other information that is deemed necessary for the event.

6. Submit a conference summary report to OSDBU no later than 5 business days after participation in the event or conference. The conference summary report must summarize activities, contacts, outreach results, and recommendations for continued or discontinued participation in future similar events sponsored by that organization.

7. Upon request by OSDBU, coordinate efforts with DOT's grantees and recipients at the state and/or local levels to sponsor or cosponsor an OSDBU transportation related conference in the region.

8. Participate in monthly teleconference call with the Regional Assistance Division Manager and OSDBU staff.

(F) Short Term Lending Program (STLP)

1. Work with STLP participating banks and if not available, other lending institutions to deliver a minimum of five (5) seminars/workshops per year on the STLP financial assistance program to the transportation-related small business community. The seminar/workshop must cover the entire STLP process, from completion of STLP loan applications and preparation of the loan package to graduation from the STLP.

2. Provide direct support, technical support, and advocacy services to potential STLP applicants to increase the probability of STLP loan approval and generate a minimum of seven (7) completed STLP applications per year.

(G) Bonding Education Program (BEP)

Work with OSDBU, bonding industry partners, local small business transportation stakeholders, and local bond producers/agents in your region to deliver a minimum of 2 complete BEP seminars. The BEP consists of the following components; 1) the stakeholder's meeting; 2) the educational workshops component; 3) the bond readiness component; and 4) follow-on assistance to BEP participants via technical and procurement assistance based on the prescriptive plan determined by the BEP. For each BEP event, work with the local bond producers/agents in your region and the disadvantaged business participants to deliver minimum of 10 disadvantaged business participants in the BEP event with either access to bonding or an increase in bonding capacity.

Furnish all labor, facilities and equipment to perform the services described in this announcement.

(H) Women and Girls in Transportation Initiative (WITI)

Pursuant to Executive Order 13506, and 49 U.S.C. § 332(b)(4) & (7), the SBTRC shall administer the WITI in their geographical region. The SBTRC shall implement the DOT WITI program as defined by the DOT WITI Policy. The WITI program is designed to identify, educate, attract, retain women and girls from a variety of disciplines in the transportation industry. The SBTRC shall also be responsible for outreach activities in the implementation of this program and advertising the WITI program to all colleges and universities and transportation entities in their region. The WITI program shall be developed in conjunction with the skill needs of the USDOT, state and local transportation agencies and appropriate private sector transportation-related participants including, S/WOBs/DBEs, and women organizations involved in transportation. Emphasis shall be placed on establishing partnerships with transportation-related businesses. The SBTRC will be required to host 1 WITI event and attend at least 5 events where WITI is presented and marketed.

2.2 Office of Small and Disadvantaged Business Utilization (OSDBU) Responsibilities

(A) Provide consultation and technical assistance in planning, implementing and evaluating activities under this announcement.

(B) Provide orientation and training to the applicant organization.

(C) Monitor SBTRC activities, cooperative agreement compliance, and overall SBTRC performance.

(D) Assist SBTRC to develop or strengthen its relationships with federal, state, and local transportation authorities, other technical assistance organizations, and DOT grantees.

(E) Facilitate the exchange and transfer of successful program activities and information among all SBTRC regions.

(F) Provide the SBTRC with DOT/OSDBU materials and other relevant transportation related information for dissemination.

(G) Maintain effective communication with the SBTRC and inform them of transportation news and contracting opportunities to share with small businesses in their region.

(H) Provide all required forms to be used by the SBTRC for reporting purposes under the program.

(I) Perform an annual performance evaluation of the SBTRC. Satisfactory performance is a condition of continued participation of the organization as an SBTRC and execution of all option years.

3. Submission of Proposals

3.1 Format for Proposals

Each proposal must be submitted to DOT's OSDBU in the format set forth in the application form attached as Appendix A to this announcement.

3.2 Address; Number of Copies; Deadlines for Submission

Any eligible organization, as defined in Section 1.6 of this announcement, will submit only one proposal per state for consideration by OSDBU.

Applications must be double spaced, and printed in a font size not smaller than 12 points. Applications will not exceed 35 single-sided pages, not including any requested attachments. All pages should be numbered at the top of each page. All documentation, attachments, or other information pertinent to the application must be included in a single submission. Proposal packages must be submitted electronically to OSDBU at *SBTRC@dot.gov.*

The applicant is advised to turn on request delivery receipt notification for

email submission. Proposals must be received by DOT/OSDBU no later than March 14, 2014 6:00 p.m. Eastern Standard Time (EST).

4. Selection Criteria

4.1 General Criteria

OSDBU will award the cooperative agreement on a best value basis, using the following criteria to rate and rank applications:

Applications will be evaluated using a point system (maximum number of points = 100);

- Approach and strategy (25 points)
- Linkages (25 points)
- Organizational Capability (25 points)
- Staff Capabilities and Experience (15 points)
- Cost Proposal (10 points)

(A) Approach and Strategy (25 Points)

The applicant must describe their strategy to achieve the overall mission of the SBTRC as described in this solicitation and service the small business community in their entire geographic regional area. The applicant must also describe how the specific activities outlined in Section 2.1 will be implemented and executed in the organization's regional area. OSDBU will consider the extent to which the proposed objectives are specific, measurable, time-specific, and consistent with OSDBU goals and the applicant organization's overall mission. OSDBU will give priority consideration to applicants that demonstrate innovation and creativity in their approach to assist small businesses to become successful transportation contractors and increase their ability to access DOT contracting opportunities and financial assistance programs. Applicants must also submit the estimated direct costs, other than labor, to execute their proposed strategy. OSDBU will consider the quality of the applicant's plan for conducting program activities and the likelihood that the proposed methods will be successful in achieving proposed objectives at the proposed cost.

(B) Linkages (25 Points)

The applicant must describe their established relationships within their geographic region and demonstrate their ability to coordinate and establish effective networks with DOT grant recipients and local/regional technical assistance agencies to maximize resources. OSDBU will consider innovative aspects of the applicant's approach and strategy to build upon their existing relationships and established networks with existing resources in their geographical area. The applicant should describe their strategy to obtain support and collaboration on SBTRC activities from DOT grantees and recipients, transportation prime contractors and subcontractors, the SBA, U.S. Department of Commerce's Minority Business Development Centers (MBDCs), Service Corps of Retired Executives (SCORE), Procurement Technical Assistance Centers (PTACs), Small Business Development Centers (SBDCs), State DOTs, and State highway supportive services contractors. In rating this factor, OSDBU will consider the extent to which the applicant demonstrates ability to be multidimensional. The applicant must demonstrate that they have the ability to access a broad range of supportive services to effectively serve a broad range of transportation-related small businesses within their respective geographical region. Emphasis will also be placed on the extent to which the applicant identifies a clear outreach strategy related to the identified needs that can be successfully carried out within the period of this agreement and a plan for involving the Planning Committee in the execution of that strategy.

(C) Organizational Capability (25 Points)

The applicant must demonstrate that they have the organizational capability to meet the program requirements set forth in Section 2. The applicant organization must have sufficient resources and past performance experience to successfully provide outreach to the small business transportation resources in their geographical area and carry out the mission of the SBTRC. In rating this factor, OSDBU will consider the extent to which the applicant's organization has recent, relevant and successful experience in advocating for and addressing the needs of small businesses. Applicants will be given points for demonstrated past transportation-related performance. The applicant must also describe technical and administrative resources it plans to use in achieving proposed objectives. In their description, the applicant must describe their facilities, computer and technical facilities, ability to tap into volunteer staff time, and a plan for sufficient matching alternative financial resources to fund the general and administrative costs of the SBTRC. The applicant must also describe their administrative and financial management staff. It will be the responsibility of the successful candidate to not only provide the services outlined herein to small businesses in the transportation industry, but to also successfully manage and maintain their internal financial, payment, and invoicing process with their financial management offices. OSDBU will place an emphasis on capabilities of the applicant's financial management staff. Additionally a site visit will be required prior to award for those candidates that are being strongly considered. A member of the OSDBU team will contact those candidates to schedule the site visits prior to the award of the agreement.

(D) Staff Capability and Experience (15 Points)

The applicant organization must provide a list of proposed personnel for the project, with salaries, fringe benefit burden factors, educational levels and previous experience clearly delineated. The applicant's project team must be well-qualified, knowledgeable, and able to effectively serve the diverse and broad range of small businesses in their geographical region. The Executive Director and the Project Director shall be deemed key personnel. Detailed resumes must be submitted for all proposed key personnel and outside consultants and subcontractors. Proposed key personnel must have detailed demonstrated experience providing services similar in scope and nature to the proposed effort. The proposed Project Director will serve as the responsible individual for the program. 100% of the Project Director's time must be dedicated to the SBTRC. Both the Executive Director and the Project Director must be located on-site. In this element, OSDBU will consider the extent to which the applicant's proposed Staffing Plan; (a) clearly meets the education and experience requirements to accomplish the objectives of the cooperative agreement; (b) delineates staff responsibilities and accountability for all work required and; (c) presents a clear and feasible ability to execute the applicant's proposed approach and strategy.

(E) Cost Proposal (10 Points)

Applicants must submit the total proposed cost of establishing and administering the SBTRC in the applicant's geographical region for a 12 month period, inclusive of costs funded through alternative matching resources. The applicant's budget must be adequate to support the proposed strategy and costs must be reasonable in relation to project objectives. The portion of the submitted budget funded by OSDBU cannot exceed the ceiling

outlined in Section 1.3: Description of Competition of this RFP per fiscal year. Applicants are encouraged to provide in-kind costs and other innovative cost approaches.

4.2 Scoring of Applications

A review panel will score each application based upon the evaluation criteria listed above. Points will be given for each evaluation criteria category, not to exceed the maximum number of points allowed for each category. Proposals which are deemed non–responsive, do not meet the established criteria, or incomplete at the time of submission will be disqualified.

OSDBU will perform a responsibility determination of the prospective awardee in the region, which may include a site visit, before awarding the cooperative agreement.

4.3 Conflicts of Interest

Applicants must submit signed statements by key personnel and all organization principals indicating that they, or members of their immediate families, do not have a personal, business or financial interest in any DOT-funded transportation project, nor any relationships with local or state transportation agencies that may have the appearance of a conflict of interest.

Appendix A

Format for Proposals for the Department of Transportation Office of Small and Disadvantaged Business Utilization's Small Business Transportation Resource Center (SBTRC) Program

Submitted proposals for the DOT, Office of Small and Disadvantaged Business Utilization's Small Business Transportation Resource Center Program must contain the following 12 sections and be organized in the following order:

1. TABLE OF CONTENTS

Identify all parts, sections and attachments of the application.

2. APPLICATION SUMMARY

Provide a *summary overview* of the following:

- The applicant's proposed SBTRC region and city and key elements of the plan of action/strategy to achieve the SBTRC objectives.
- The applicant's relevant organizational experience and capabilities.

3. UNDERSTANDING OF THE WORK

Provide a narrative which contains specific project information as follows:

- The applicant will describe its understanding of the OSDBU's SBTRC program mission and the role of the applicant's proposed SBTRC in advancing the program goals.
- The applicant will describe specific outreach needs of transportation-related small businesses in the applicant's region and how the SBTRC will address the identified needs.

4. APPROACH AND STRATEGY

- Describe the applicant's plan of action/strategy for conducting the program in terms of the tasks to be performed.
- Describe the specific services or activities to be performed and how these services/activities will be implemented.
- Describe innovative and creative approaches to assist small businesses to become successful transportation contractors and increase their ability to access DOT contracting opportunities and financial assistance programs.
- Estimated direct costs, other than labor, to execute the proposed strategy.

5. LINKAGES

- Describe established relationships within the geographic region and demonstrate the ability to coordinate and establish effective networks with DOT grant recipients and local/regional technical assistance agencies.
- Describe the strategy to obtain support and collaboration on SBTRC activities from DOT grantees and recipients, transportation prime contractors and subcontractors, the SBA, U.S. Department of Commerce's Minority Business Development Centers (MBDCs), Service Corps of Retired Executives (SCORE), Procurement Technical Assistance Centers (PTACs), Small Business Development Centers (SBDCs), State DOTs, and State highway supportive services contractors.
- Describe the outreach strategy related to the identified needs that can be successfully carried out within the period of this agreement and a plan for involving the Planning Committee in the execution of that strategy.

6. ORGANIZATIONAL CAPABILITY

- Describe recent and relevant past successful performance in addressing the needs of small businesses, particularly with respect to transportation-related small businesses.
- Describe internal technical, financial management, and administrative resources.
- Propose a plan for sufficient matching alternative financial resources to fund the general and administrative costs of the SBTRC.

7. STAFF CAPABILITY AND EXPERIENCE

- List proposed key personnel, their salaries and proposed fringe benefit factors.
- Describe the education, qualifications and relevant experience of key personnel. Attach detailed resumes.
- Proposed staffing plan. Describe how personnel are to be organized for the program and how they will be used to accomplish program objectives. Outline staff responsibilities, accountability and a schedule for conducting program tasks.

8. COST PROPOSAL

- Outline the total proposed cost of establishing and administering the SBTRC in the applicant's geographical region for a 12 month period, inclusive of costs funded through alternative matching resources. Clearly identify the portion of the costs funded by OSDBU.
- Provide a brief narrative linking the cost proposal to the proposed strategy.

9. PROOF OF TAX EXEMPT STATUS

10. ASSURANCES SIGNATURE FORM

Complete the attached Standard Form 424B ASSURANCES–NON–CONSTRUCTION PROGRAMS identified as Attachment 1.

11. CERTIFICATION SIGNATURE FORMS

Complete form DOTF2307–1 DRUG-FREE WORKPLACE ACT CERTIFICATION FOR a GRANTEE OTHER THAN AN INDIVIDUAL identified as attachment 2 and Form DOTF2308–1 CERTIFICATION REGARDING LOBBYING FOR CONTRACTS, GRANTS, LOANS, AND COOPERATIVE AGREEMENTS identified as Attachment 3.

SIGNED CONFLICT OF INTEREST STATEMENTS

The statements must say that they, or members of their immediate families, do not have a personal, business or financial interest in any DOT-funded transportation projects, nor any relationships with local or state transportation agencies that may have the appearance of a conflict of interest.

12. STANDARD FORM 424

Complete Standard Form 424 Application for Federal Assistance identified as Attachment 4.

PLEASE BE SURE THAT ALL FORMS HAVE BEEN SIGNED BY AN AUTHORIZED OFFICIAL WHO CAN LEGALLY REPRESENT THE ORGANIZATION.

Issued in Washington, DC, on February 10, 2014

Brandon Neal,

Director, Office of Small and Disadvantaged Business Utilization, Office of the Secretary, U.S. Department of Transportation.

[FR Doc. 2014–04155 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No: FAA–2011–0786]

Deadline for Notification of Intent To Use the Airport Improvement Program (AIP) Primary, Cargo, and Nonprimary Entitlement Funds for Fiscal Year 2014.

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces May 1, 2014, as the deadline for each airport sponsor to notify the FAA whether or not it will use its fiscal year 2014 entitlement funds available under Section 47114 of Title 49, United States Code, to accomplish Airport Improvement Program (AIP)-eligible

projects that the sponsor previously identified through the Airports Capital Improvement Plan (ACIP) process during the preceding year.

The sponsor's notification must address all entitlement funds apportioned for fiscal year 2014, as well as any entitlement funds not obligated from prior years. After Friday, July 11, 2014, the FAA will carry over all remaining entitlement funds, and the funds will not be available again until at least the beginning of fiscal year 2015. This notification requirement does not apply to non-primary airports covered by the block-grant program.

FOR FURTHER INFORMATION CONTACT: Mr. Frank J. San Martin, Manager, Airports Financial Assistance Division, APP–500, on (202) 267–3831.

SUPPLEMENTARY INFORMATION: Title 49 of the United States Code, section 47105(f), provides that the sponsor of each airport to which funds are apportioned shall notify the Secretary by such time and in a form as prescribed by the Secretary, of the sponsor's intent to apply for its apportioned funds, also called entitlement funds. Therefore, the FAA is hereby notifying sponsors about steps required to ensure that the FAA has sufficient time to carryover and convert remaining entitlement funds, due to processes required under federal laws. This notice applies only to those airports that have had entitlement funds apportioned to them, except those nonprimary airports located in designated Block Grant States. Sponsors intending to apply for any of their available entitlement funds, including those unused from prior years, shall submit by 12:00 p.m. prevailing local time on Thursday, May 1, 2014, a written indication to the designated Airports District Office (or Regional Office in regions without Airports District Offices) their intent to submit a grant application no later than close of business Friday, July 11, 2014, to use their fiscal year 2014 entitlement funds available under Title 49 of the United States Code, section 47114. This notice must address all entitlement funds apportioned for fiscal year 2014 including those entitlement funds not obligated from prior years. By Friday, June 13, 2014, airport sponsors that have not yet submitted a final application to the FAA, should notify the FAA of any issues with meeting the final application deadline of July 11, 2014. Absent notification from the sponsor by the May 1st deadline and/or subsequent notification by the June 13th deadline of any issues with meeting the application deadline, the FAA will proceed after Friday, July 11, 2014 to take action to carry over all remaining entitlement funds without further notice. The funds will not be available again until at least the beginning of fiscal year 2015.

This notice is promulgated to expedite and facilitate the grant-making process.

The AIP grant program is operating under the requirements of Public Law No. 112–91, the ''FAA Modernization and Reform Act of 2012,'' enacted on February 14, 2012, which authorizes the FAA through September 30, 2015 and the ''Consolidated Appropriations Act, 2014'' which appropriates FY 2014 funds for the AIP.

Issued in Washington, DC, on February 20, 2014.

Elliott Black,

Deputy Director, Office of Airport Planning and Programming.

[FR Doc. 2014–04223 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–18]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATE: Comments on this petition must identify the petition docket number and must be received on or before March 18, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2013–1049 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tara Fitzgerald, Federal Aviation Administration, Engine and Propeller Directorate, Standards Staff, ANE–111, 12 New England Executive Park, Burlington, Massachusetts 01803–5229; (781) 238–7130; facsimile: (781) 238–7199; email: *tara.fitzgerald@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on February 20, 2014.

Lirio Liu,

Director, Office of Rulemaking.

PETITION FOR EXEMPTION

Docket No.: FAA–2013–1049

Petitioner: Rolls-Royce plc

Section of 14 CFR Affected: 14 CFR 33.27H2(f)(6)

Description of Relief Sought: Petitioner seeks relief from requirement of section 33.27(f)(6), which prohibits the exclusion of the entire high-pressure shaft system from consideration in determining the highest over-speed that would result from a complete loss of load on a turbine rotor. The relief is sought for the Trent 1000–A2, C2, D2, E2, G2, H2, J2, K2 and L2 engine models.

[FR Doc. 2014–04115 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2013–61]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before March 18, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2013–1006 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Keira Jones (202) 267–4024 or Nia Daniels (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on February 20, 2014.

Lirio Liu,

Director, Office of Rulemaking.

Petition For Exemption

Docket No.: FAA–2013–1006
Petitioner: Allegiant Air, LLC
Section of 14 CFR Affected:
§ 121.413(a)(2)

Description of Relief Sought: Allegiant Air is seeking relief from § 121.413(a)(2) that would allow it to substitute a qualified and authorized Check Airman in place of an Federal Aviation Administration inspector to observe a qualifying Check Airman while that Check Airman is performing prescribed checking duties when completing initial Check Airman training.

Project No.: AFS–14–048–E
Project Officer:_____
ARM–108:NDaniels:12/12/2013:Doc# 37418
ARM–1/100/108:Program Office AFS–200

[FR Doc. 2014–04113 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2014–17]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before March 18, 2014.

ADDRESSES: You may send comments identified by Docket Number FAA–2013–0969 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Forseth, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, phone 425–306–7134, email mark.forseth@faa.gov; or Sandra Long, ARM–201, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, phone (202) 493–5245, email *sandra.long@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on February 20, 2014.

Lirio Liu,

Director, Office of Rulemaking.

PETITION FOR EXEMPTION

Docket No.: FAA–2013–0969.

Petitioner: Airbus SAS.

Section of 14 CFR Affected: 14 CFR 25.809(a).

Description of Relief Sought: Airbus seeks relief from the requirements of outside viewing from the flight-deck emergency exit for Airbus Model A350 airplanes.

[FR Doc. 2014–04114 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Statute of Limitations on Claims; Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project, US Route 101 from 1.1 mile north of the Mendocino County line to 2.2 miles north of the Mendocino County line in Humboldt County, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before July 28, 2014. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*) (1) by issuing licenses, permits, and approvals for the following highway project in the State of *California:* Richardson Grove Operational Improvement Project to provide Surface Transportation Assistance Act (STAA) access on US Route 101. Project limit is from 1.1 mile north of the Mendocino County line to 2.2 miles north of the Mendocino County line and would include minor curve realignments, drainage improvements, shoulder widening, cuts and fills, and a retaining wall. The actions by the Federal agency, and the laws under which such actions were taken, are described in the Final Environmental Assessment/Finding of No Significant Impact (FONSI) for the project, approved on May 18, 2010; the Supplement to the Final EA and Reevaluation of the FONSI, approved on January 24, 2014; and in other documents in the FHWA project records. The FEA, FONSI, Supplement, Reevaluation and other project records are available by contacting Caltrans at the address provided above. The Caltrans FEA, FONSI and Supplement can be viewed and downloaded from the project Web site at *www.dot.ca.gov/dist1/d1projects/richardson_grove/.* This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to

1. Endangered Species Act
2. National Historic Preservation Act of 1966 as amended
3. Wild and Scenic Rivers Act
4. Section 4(f) of the Department of Transportation Act of 1966
5. Clean Water Act
6. National Environmental Policy Act (NEPA)

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

FOR FURTHER INFORMATION CONTACT: For *Caltrans:* Valerie Gizinski, Senior Environmental Planner, North Region Environmental Services, P.O. Box 3700, Eureka, CA 95502, 8:00 a.m. to 5:00 p.m., (707) 445–5320, *valerie_gizinski@dot.ca.gov.*

Issued on: February 20, 2014.

Gary Sweeten,

Team Leader North, Project Delivery, Federal Highway Administration, Sacramento, California.

[FR Doc. 2014–04143 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–MARAD 2014–0022]

Agency Requests for Renewal of a Previously Approved Information Collection: Uniform Financial Reporting Requirements

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information collection is necessary for MARAD to determine compliance with regulatory and contractual requirements. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995, Public Law 104–13.

DATES: Written comments should be submitted by April 28, 2014.

ADDRESSES: You may submit comments [identified by Docket No. DOT–MARAD–2014–0022 through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Daniel Ladd, Office of Financial Approvals and Marine Insurance, Division of Business Finance, 202–366–1859, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W23–322, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2133–0005

Title: Uniform Financial Reporting Requirements

Form Numbers: MA–172

Type of Review: Renewal of a previously approved information collection.

Background: The Uniform Financial Reporting Requirements are used as a basis for preparing and filing semi-annual and annual financial statements with the Maritime Administration. Regulations requiring financial reports to the Maritime Administration are authorized by Section 801 of the Merchant Marine Act, 1936 (46 U.S.C. 53101 note). Financial reports are also

required by regulation of purchasers of ships from MARAD on credit, companies chartering ships from MARAD, and of companies having Title XI guarantee obligations (46 CFR Part 298).

Respondents: Vessel owners acquiring ships from MARAD on credit, companies chartering ships from MARAD, and companies having Title XI guarantee obligations.

Number of Respondents: 66

Frequency: Bi-annually

Number of Responses: 132

Total Annual Burden: 1254 hours

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

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) or you may visit *http://regulations.gov.*

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1:93.

Dated: February 18, 2014.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2014–04229 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2014 0019]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel E SEA GIRL; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before March 28, 2014.

ADDRESSES: Comments should refer to docket number MARAD–2014–0019. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel E SEA GIRL is:

Intended Commercial Use Of Vessel: ''custom charters''

Geographic Region: ''Hawaii''

The complete application is given in DOT docket MARAD–2014–0019 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: February 18, 2014.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2014–04225 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2014 0021]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ISLAND ESCAPE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before March 28, 2014.

ADDRESSES: Comments should refer to docket number MARAD–2014–0021. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ISLAND ESCAPE is:

Intended Commercial Use of Vessel: ''Excursions, sunset cruises, photo shoots, and special events, carrying up to six passengers''

Geographic Region: ''Connecticut, Rhode Island, Massachusetts, New York, and New Jersey''

The complete application is given in DOT docket MARAD–2014–0021 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: February 18, 2014.

By Order of the Maritime Administrator.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2014–04228 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2014 0020]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CORSAIR; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before March 28, 2014.

ADDRESSES: Comments should refer to docket number MARAD–2014–0020. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov*. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov*.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CORSAIR is:

Intended Commercial Use of Vessel: ''Team building events, racing and sailing lessons''

Geographic Region: ''New York, New Jersey and Connecticut''

The complete application is given in DOT docket MARAD–2014–0020 at *http://www.regulations.gov*. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Date: February 18, 2014.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2014–04227 Filed 2–25–14; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

February 20, 2014.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before March 28, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania

Ave., NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at PRA@treasury.gov, or the entire information collection request maybe found at *www.reginfo.gov.*

Terrorism Risk Insurance Program (TRIP)

OMB Number: 1505–0200.

Type of Review: Revision of a currently approved collection.

Title: Terrorism Risk Insurance Program Loss Reporting.

Form: TRIP 01, 02, 02A, 02B, and 02C.

Abstract: Information collection made necessary by the Terrorism Risk Insurance Act of 2002, as amended by the Terrorism Risk Insurance Extension Act of 2005, the Terrorism Risk Insurance Program Reauthorization Act of 2007, and by Treasury implementing regulations to pay the Federal share to commercial property and casualty insurers for terrorism losses.

Affected public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 4,200.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2014–04098 Filed 2–25–14; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

February 21, 2014.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before March 28, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8141, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 622–1295, emailing *PRA@treasury.gov*, or the entire information collection request may be found at *www.reginfo.gov.*

Bureau of the Fiscal Service

OMB Number: 1535–0141.

Type of Review: Revision of a currently approved collection.

Title: Investigative Forms.

Form: PD F 5518, PD F 5519, PD F 5520, and PD F 5521.

Abstract: Information requested is in support of background investigations conducted by the Bureau of the Fiscal Service to determine suitability for employment or security clearance.

Affected Public: Individuals or households.

Estimated Annual Burden Hours: 125.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2014–04149 Filed 2–25–14; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8947

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 Form 8947, Report of Branded Prescription Drug Information.

DATES: Written comments should be received on or before April 28, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to 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: Report of Branded Prescription Drug Information.

OMB Number: 1545–2192.

Form Number: Form 8947.

Abstract: Report of Covered Pharmaceutical Manufacturers and Importers allows for fee to be assessed against entities selling branded prescription drugs to specified government agencies, based in part on controlled group status and credits allowed for qualified ''orphan drugs''.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 400.

Estimated Time per Respondent Recordkeeping: 7 Hours, 24 minutes.

Estimated Time per Respondent Learning: 42 minutes.

Estimated Time per Respondent Preparing: 51 minutes.

Estimated Total Annual Burden Hours: 3,584 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: February 12, 2014.

Joseph Durbala,

Tax Analyst.

[FR Doc. 2014–04218 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 13551

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 Form 13551, Application to Participate in the IRS Acceptance Agent Program.

DATES: Written comments should be received on or before April 28, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to 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: Application to Participate in the IRS Acceptance Agent Program.

OMB Number: 1545–1896.

Form Number: 13551.

Abstract: Form 13551 is used to gather information to determine applicant's eligibility in the Acceptance Agent Program.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, not-for-profit institutions, and Federal, state, local or tribal government.

Estimated Number of Respondents: 12,825.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 6,413.

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: February 19, 2014.

Joseph Durbala,

Tax Analyst.

[FR Doc. 2014–04204 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Monday, March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Patricia Robb or Ellen Smiley at 1–888–912–1227 or (414) 231–2360.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Monday, March 31, 2014, at 1:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Patricia Robb or Ellen Smiley. For more information please contact Patricia Robb or Ellen Smiley at 1–888–912–1227 or (414) 231–2360 or write: TAP Office, Stop 1006MIL, 211 West Wisconsin Avenue, Milwaukee, WI 53203–2221 or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: February 20, 2014.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2014–04217 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meetings will be held Monday, March 24, 2014 and Tuesday, March 25, 2014.

FOR FURTHER INFORMATION CONTACT: Timothy Shepard at 1–888–912–1227 or 206–220–6095.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988)

that a meeting of the Taxpayer Advocacy Panel Notices and Correspondence Project Committee will be held Monday, March 24, 2014, from 1:00 p.m. to 4:30 p.m., and Tuesday, March 25, 2014, from 8:00a.m. to 4:30p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Timothy Shepard. For more information please contact Mr. Shepard at 1–888–912–1227 or 206–220–6095, or write TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include a discussion on various letters, and other issues related to written communications from the IRS.

Dated: February 20, 2014.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2014–04214 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meetings will be held Thursday, March 20 and Friday March 21, 2014.

FOR FURTHER INFORMATION CONTACT: Donna Powers at 1–888–912–1227 or (954) 423–7977.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be held Thursday, March 20, 2014 from 8:00 a.m. to 4:30 p.m. and Friday, March 21, 2014, from 8:00a.m. to 12:00p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Donna Powers. For more information please contact Ms. Powers at 1–888–912–1227 or (954) 423–7977 or write: TAP Office, 1000 S. Pine Island Road, Plantation, FL 33324 or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: February 20, 2014.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2014–04213 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meetings will be held Monday, March 24, 2014 and Tuesday, March 25, 2014.

FOR FURTHER INFORMATION CONTACT: Trena Derricott at 1–888–912–1227 or 801–620–3035

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Tax Forms and Publications Project Committee will be held Monday, March 24, 2014, from 1:00p.m. to 4:30p.m. and Tuesday, March 25, 2014, from 8:00a.m. to 4:30p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Ms. Derricott. For more information please contact Ms. Derricott at 1–888–912–1227 or 801–620–3035, or write TAP Office, Arka Monterey Park Building, 1973 North Rulon White Blvd., Ogden, UT 84404–5402 or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to Tax Forms and Publications and public input is welcomed.

Dated: February 20, 2014.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2014–04215 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Recruitment Notice for the Taxpayer Advocacy Panel

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice.

SUMMARY: Notice of Open Season for Recruitment of IRS Taxpayer Advocacy Panel (TAP) Members.

DATES: March 7, 2014, through April 11, 2014.

FOR FURTHER INFORMATION CONTACT: Sheila Andrews at 317–685–7596 (not a toll-free call).

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Department of the Treasury and the Internal Revenue Service are inviting individuals to help improve the nation's tax agency by applying to be members of the Taxpayer Advocacy Panel. The mission of the TAP is to listen to taxpayers, identify issues that affect taxpayers, and make suggestions for improving IRS service and customer satisfaction. The TAP serves as an advisory body to the Secretary of the Treasury, the Commissioner of Internal Revenue, and the National Taxpayer Advocate. Taxpayer Advocacy Panel members will participate in subcommittees that channel their feedback to the IRS through the Panel's parent committee.

The IRS is seeking applicants who have an interest in good government, a personal commitment to volunteer approximately 200 to 300 hours a year, and a desire to help improve IRS customer service. To the extent possible, the TAP Director will ensure that TAP membership is balanced and represents a cross-section of the taxpaying public with at least one member from each state, the District of Columbia and Puerto Rico. In addition, the TAP is seeking to include at least one member representing international taxpayers. For these purposes, ''international taxpayers'' are broadly defined to include U.S. citizens working, living, or doing business abroad or in a U.S. territory. Potential candidates must be U.S. citizens and must pass an IRS tax compliance check and a Federal Bureau

of Investigation background investigation. Federally-registered lobbyists cannot be members of the TAP.

Taxpayer Advocacy Panel members are a diverse group of citizens who represent the interests of taxpayers from their respective geographic locations by providing feedback from a taxpayer's perspective on ways to improve IRS customer service and administration of the federal tax system, and by identifying grassroots taxpayer issues. Members should have good communications skills and be able to speak to taxpayers about the TAP and TAP activities, while clearly distinguishing between TAP positions and their personal viewpoints.

Interested applicants should visit the TAP Web site at *www.improveirs.org* to complete the on-line application or call the TAP toll-free number, 1–888–912–1227, if they have questions about TAP membership. The opening date for submitting applications is February 7, 2014, and the deadline for submitting applications is April 11, 2014. Interviews may be held. The Department of the Treasury will review the recommended candidates and make final selections. New TAP members will serve a three-year term starting in December 2014. (Note: Highly-ranked applicants not selected as members may be placed on a roster of alternates who will be eligible to fill future vacancies that may occur on the Panel.)

Questions regarding the selection of TAP members may be directed to Sheila Andrews, Director, Taxpayer Advocacy Panel, Internal Revenue Service, 1111 Constitution Avenue NW., TA:TAP Room 1509, Washington, DC 20224, or 317–685–7596 (not a toll-free call).

Dated: February 20, 2014.

Otis Simpson,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2014–04216 Filed 2–25–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0546]

Agency Information Collection (Gravesite Reservation Survey (2 Year)) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before March 28, 2014.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0546'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632–7492 or email *crystal.rennie@va.gov.* Please refer to ''OMB Control No. 2900–0546.''

SUPPLEMENTARY INFORMATION:

Title: Gravesite Reservation Survey (2 Year), VA Form 40–40.

OMB Control Number: 2900–0546.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form Letter 40–40 is sent biennially to individuals holding gravesite set-asides to ascertain their wish to retain the set-aside, or relinquish it. Gravesite reservation surveys are necessary as some holders become ineligible, are buried elsewhere, or simply wish to cancel a gravesite set-aside. The survey is conducted to assure that gravesite set-asides do not go unused.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on November 15, 2013, at page 68909.

Affected Public: Individuals or households, Business or other for profit.

Estimated Annual Burden: 2,750.

Estimated Average Burden Per Respondent: 10 minutes.

Frequency of Response: Biennially.

Estimated Number of Respondents: 16,500.

Dated: February 20, 2014.

By direction of the Secretary.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2014–04060 Filed 2–25–14; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Clinical Science Research and Development Service Cooperative Studies Scientific Evaluation Committee; Notice of Meeting

The Department of Veterans Affairs gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Clinical Science Research and Development Service Cooperative Studies Scientific Evaluation Committee will hold a meeting on March 13, 2014, at the American Association of Airport Executives, 601 Madison Street, Alexandria, VA. The meeting will begin at 8:30 a.m. and end at 12:00 p.m.

The Committee advises the Chief Research and Development Officer through the Director of the Clinical Science Research and Development Service on the relevance and feasibility of proposed projects and the scientific validity and propriety of technical details, including protection of human subjects.

The session will be open to the public for approximately 30 minutes at the start of the meeting for the discussion of administrative matters and the general status of the program. The remaining portion of the meeting will be closed to the public for the Committee's review, discussion, and evaluation of research and development applications.

During the closed portion of the meeting, discussions and recommendations will deal with qualifications of personnel conducting the studies, staff and consultant critiques of research proposals and similar documents, and the medical records of patients who are study subjects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. As provided by section 10(d) of Public Law 92–463, as amended, closing portions of this meeting is in accordance with 5 U.S.C. 552b(c)(6) and (c)(9)(B).

The Committee will not accept oral comments from the public for the open portion of the meeting. Those who plan to attend or wish additional information should contact Dr. Grant Huang, Acting Director, Cooperative Studies Program (10P9CS), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at (202) 443–

5700 or by email at *grant.huang@va.gov.* Those wishing to submit written comments may send them to Dr. Huang at the same address and email.

Dated: February 21, 2014.

Rebecca Schiller,

Committee Management Officer.

[FR Doc. 2014–04154 Filed 2–25–14; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Part 170

Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB92

Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Notice of proposed rulemaking with comment period.

SUMMARY: This notice of proposed rulemaking introduces the beginning of the Office of National Coordinator for Health Information Technology's (ONC's) more frequent approach to health information technology certification regulations. Under this approach ONC intends to update certification criteria editions every 12 to 18 months in order to provide smaller, more incremental regulatory changes and policy proposals. This approach gives stakeholders greater and earlier visibility into our regulatory direction before compliance is required, provides more time for public input on policy proposals under consideration for future rulemakings, and enables our certification processes to more quickly adopt newer industry standards that can enhance interoperability.

The 2015 Edition EHR certification criteria proposed in this rule would be voluntary. *No* EHR technology developer who has certified its EHR technology to the 2014 Edition would need to recertify to the 2015 Edition in order for its customers to participate in the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs). Furthermore, eligible professionals, eligible hospitals, and critical access hospitals that participate in the EHR Incentive Programs *would not* need to ''upgrade'' to EHR technology certified to 2015 Edition in order to have EHR technology that meets the Certified EHR Technology (CEHRT) definition. Instead, the 2015 Edition EHR certification criteria would accomplish three policy objectives: 1) They would enable a more efficient and effective response to stakeholder feedback; 2) they would incorporate ''bug fixes'' to improve on 2014 Edition EHR certification criteria in ways designed to make our rules clearer and easier to implement; and 3) they reference newer standards and implementation specifications that reflect our commitment to promoting innovation and enhancing interoperability.

Specific revisions to the ONC HIT Certification Program are also included in this proposed rule. These proposals focus on: Improving regulatory clarity; simplifying the certification of EHR Modules that are designed for purposes other than achieving meaningful use; and discontinuing the use of the Complete EHR definition starting with the 2015 Edition.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on April 28, 2014.

ADDRESSES: You may submit comments, identified by RIN 0991–AB92, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov*.
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 2015 Edition EHR Standards and Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201. Please submit one original and two copies.
- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 2015 Edition EHR Standards and Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To enhance the accessibility and ease with which the public may comment on this proposed rule, a copy will be made available in Microsoft Word format. We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document will be made available for the public to use to provide comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on the certification criteria, associated standards and implementation specifications, and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments or to use it as an addendum to narrative cover pages. Roughly 30% of the public comments submitted to our 2014 Edition notice of proposed rulemaking used the provided template, which greatly assisted in our ability to rapidly process and more accurately categorize public comments. Because of the technical nature of this proposed rule, we believe that use of the document may facilitate our review and understanding of the comments received. The Microsoft Word version of the proposed rule and the document that can be used for providing comments can be found at *http://www.regulations.gov* as part of this proposed rule's docket and on ONC's Web site (*http://www.healthit.gov*).

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *http://www.regulations.gov*.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Commonly Used Acronyms

CAH Critical Access Hospital
CDA Clinical Document Architecture
CDC Centers for Disease Control and Prevention
CDS Clinical Decision Support
CEHRT Certified Electronic Health Record Technology
CFR Code of Federal Regulations
CHPL Certified Health Information Technology Product List
CLIA Clinical Laboratory Improvement Amendments
CMS Centers for Medicare & Medicaid Services
CQM Clinical Quality Measure
CY Calendar Year
EH Eligible Hospital
EHR Electronic Health Record
EP Eligible Professional
FY Fiscal Year
HHS Department of Health and Human Services
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HITPC HIT Policy Committee
HITSC HIT Standards Committee
HL7 Health Level Seven
IG Implementation Guide
IHE Integrating the Healthcare Enterprise®
LOINC® Logical Observation Identifiers Names and Codes
MU Meaningful Use
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
NCPDP National Council for Prescription Drug Programs
NIST National Institute of Standards and Technology
PHSA Public Health Service Act
SNOMED CT® Systematized Nomenclature of Medicine Clinical Terms

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I. Executive Summary

A. Purpose of Regulatory Action

On December 6, 2013, CMS announced its intention [1] to pursue rulemaking to modify the start date of meaningful use (MU) Stage 3 for some eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs). As part of this announcement, CMS and ONC also expressed an expectation that our joint rulemaking processes to establish Stage 3 policy and supporting EHR certification criteria would result in published proposed rules in late fall 2014. Given the new (and later than originally planned) regulatory timeline, we (ONC) determined that initiating a more frequent rulemaking approach for the adoption of certification criteria would provide an opportunity to respond to stakeholder concerns regarding our prior rulemakings. Along these lines, we believe a more frequent rulemaking approach would help address both the amount of time that it takes to publish updates to our certification regulations and the corresponding impact that the infrequent, long-cycle approach has had on EHR technology development and deployment.

In the past, ONC has issued certification (program and criteria) regulations solely to support the EHR Incentive Programs. As a result, we have gained five years of process experience and stakeholder feedback. We have learned that as health information technology (HIT or health IT) continues to evolve, a two to three-year regulatory cycle is sub-optimal. Moreover, because these rulemakings have been less frequent, our regulations have had to take into account one to two years' worth of industry effort prior to the rulemaking and established policy that anticipates industry readiness one to two years post-rulemaking. This approach has created cycles of significant peaks and valleys from a health IT development standpoint; resulted in missed opportunities to improve interoperability and programmatic alignment because of mismatched regulatory and standards balloting cycle timelines; and adversely affected EHR technology developers' ability to strategically plan their development and product rollout processes due to uncertain regulatory timelines.

To address these challenges, we believe that a more incremental, frequent, and scheduled approach to publishing proposed and final rules (that is, every 12 to 18 months) would benefit the industry. We anticipate, similar to this 2015 Edition rulemaking, that some of these incremental rules would be voluntary in an effort to intentionally give EHR technology developers more time to plan, develop, and implement updated EHR technology for their customers. Overall,

[1] *http://www.cms.gov/eHealth/ListServ_Stage3 Implementation.html,*

we believe this approach will enable ONC to:

(A) Adapt our regulations to more effectively and efficiently respond to stakeholder feedback and to support HHS healthcare delivery reform and transformation programs that may seek to leverage health IT certification;

(B) Better our regulations by making ''bug fixes'' and other regulatory improvements as part of a more frequent rulemaking cycle;

(C) Chart a course toward enhanced interoperability, information exchange, quality improvement, patient engagement, and patient safety that gives health IT developers more ability to predict ONC's potential next steps; and

(D) Deliver smaller, incremental regulatory requirements that are easier to integrate into software development cycles.

The 2015 Edition rulemaking begins ONC's new regulatory approach. The proposals for the 2015 Edition in this proposed rule improve on the 2014 Edition EHR certification criteria in numerous ways. Moreover, the proposed 2015 Edition EHR certification criteria would be voluntary. In other words, *no* EHR technology developer who has certified its EHR technology to the 2014 Edition would need to recertify to the 2015 Edition in order for its customers to participate in the EHR Incentive Programs. Correspondingly, eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) that participate in the EHR Incentive Programs *would not* need to ''upgrade'' to EHR technology certified to 2015 Edition in order to have EHR technology that meets the Certified EHR Technology definition nor to standards or implementation specifications included in the 2015 Edition. *As a result, EHR technology developers and EPs, EHs, and CAHs would have the opportunity to move ahead to the 2015 Edition at their own pace and on their own terms.* Proposed new capabilities, standards-based requirements, and public comment solicitations on potential future certification criteria also provide EHR technology developers with advance visibility and time to react to the potential requirements ONC is considering for our next planned rulemaking—the 2017 Edition certification criteria (which would be proposed to support meaningful use Stage 3 proposals).

We believe the benefits of moving to the 2015 Edition for EHR technology developers and EPs, EHs, and CAHs would be three-fold:

(1) The 2015 Edition EHR certification criteria (as proposed) include updated capabilities, standards, and implementation guides (IGs) designed to enhance interoperability;

(2) Certain certification criteria changes in the 2015 Edition (as compared to the 2014 Edition and discussed in greater detail later) are designed to spur innovation, open new market opportunities, and provide more choices to EPs, EHs, and CAHs when it comes to electronic health information exchange.

(3) EHR technology developers would be able to implement regulatory updates earlier than if we would have otherwise waited another year to propose them under the new rulemaking timeline for the 2017 Edition/MU Stage 3. Along those lines, EHR technology developers that seek 2015 Edition certifications for some or all capabilities may be able to seek ''gap certification'' for those capabilities if they remain unchanged as part of the eventual 2017 Edition. Thus, EHR technology developer resources and time investments could be more spread out and lead to greater efficiency and time saved through the certification process later on. We note, however, the availability and scope of gap certification for 2015 Edition certified products to the 2017 Edition is contingent both on the outcome of the 2017 Edition rulemaking and the discretion of ONC–ACBs. For further explanation and discussion of gap certification, please see section III.C. ''Gap Certification Eligibility Table for 2015 Edition EHR Certification Criteria'' of the preamble.

B. Summary of Major Provisions

1. Overview of the 2015 Edition EHR Certification Criteria

The proposed 2015 Edition EHR certification criteria include many improvements over the 2014 Edition EHR certification criteria (*note:* hereafter, all certification criteria editions will simply be referred to by the edition year (e.g., 2015 Edition). Yet, they do not entirely overhaul the full suite of certification criteria. From a 2014 Edition perspective, we are proposing to adopt roughly 60% of the 2014 Edition EHR certification criteria without change as part of the 2015 Edition. The remaining certification criteria proposals for the 2015 Edition generally fall into four general categories:

(1) *Clarifying revisions*—consisting of clarifying regulatory text revisions. These include updating a certification criterion to reflect guidance in an already-issued frequently asked question (FAQ);

(2) *Standards updates*—to have a certification criterion reference a new standard or IG that has been published since the Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology final rule (''2014 Edition Final Rule'') was published in September 2012 (77 FR 54163 Sept. 4, 2012).

In these instances, we have considered the proposed standards consistent with the requirements of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 et. seq.) and the Office of Management and Budget (OMB) Circular A–119,[2] to use, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. In this proposed rule, we have proposed to adopt or refer to voluntary consensus standards, except for the following government-unique standards: The OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity; the transport standards proposed in § 170.202; the standard that identifies the data elements referenced by clinical quality measures (§ 170.204(c)); and certain standards related to the protection of electronic health information identified in § 170.210. We are aware of no voluntary consensus standards that would serve as alternatives to these standards for the purposes that we have identified;

(3) *Restructuring*—to make the certification criteria clearer and to improve market opportunities for diverse stakeholders to get EHR technology certified.

(4) *New certification criteria proposals*—consisting of a few new certification criteria that represent new functionality when compared to the 2014 Edition as well as some new certification criteria that are the result of splitting certain 2014 Edition certification criteria.

[2] *http://www.whitehouse.gov/omb/circulars_a119.*

2. 2017 Edition Rulemaking

To give the industry advance notice of potential proposals under consideration for future certification criteria editions and regulations (e.g., 2017 Edition), we solicit public comment on revisions we are considering to many existing certification criteria. That is, certification criteria that have been adopted as part of the 2014 Edition and proposed as part of the 2015 Edition. We include a separate preamble section that discusses and requests public comments on potential functionality and requirements for the 2017 Edition (''V. Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking''). However, please note that although we will consider the comments we receive on these issues as we develop proposals for future rulemaking, we do not plan to respond to those comments in the final rule for the 2015 Edition that we expect will follow this proposed rule.

3. ONC HIT Certification Program

We propose several modifications to the ONC HIT Certification Program's policies. We also solicit public comment on several important future program policy issues we intend to consider for our 2017 Edition rulemaking. We are proposing to simplify the certification of EHR Modules that are designed for purposes other than achieving meaningful use and to discontinue the ''Complete EHR'' certification concept, which would begin with the 2015 Edition. Every additional ONC HIT Certification Program proposal we have included focuses on clarifying regulatory text, updating existing program polices, and providing clarity for the market as it relates to EHR technology certified under the program.

C. Costs and Benefits

Our estimates indicate that this proposed rule is not an economically significant rule as its overall costs would be less than $100 million in any one year. We have, however, estimated the costs and benefits of the proposed rule. The estimated costs expected to be incurred by EHR technology developers to develop and prepare EHR technology to be tested and certified in accordance with the 2015 Edition EHR certification criteria (and the standards and implementation specifications they include) are represented in monetary terms in Table 1 below. Because the 2015 Edition is not the baseline certification criteria edition required by the CEHRT definition (as the 2014 Edition is), and because we expect our next rulemaking to adopt a 2017 Edition would commence in late calendar year 2014 and conclude in 2015, we do not believe that a large number of EHR technology developers would seek to be tested and certified to the 2015 Edition. We estimate that development and preparation efforts to the 2015 Edition would be split evenly over calendar years 2014 and 2015 and would be confined to these years because, as noted, we expect to issue a 2017 Edition final rule in 2015 and expect that the majority of EHR development and preparation efforts at that time would shift towards meeting the 2017 Edition. The dollar amounts expressed in Table 1 are expressed in 2014 dollars.

While we do not expect a majority of EHR technology developers to seek testing and certification to the 2015 Edition, it would still provide several significant benefits to patients, health care providers, and EHR technology developers. Our proposals incorporate stakeholder feedback on particular 2014 Edition issues identified as unnecessarily impeding innovation. Our proposed revisions also seek to continue to improve EHR technology's interoperability through the adoption of updated standards and implementation specifications. Furthermore, our proposal to separate the ''content'' and ''transport'' capabilities in the 2015 Edition ''transitions of care'' certification criterion (compared to the 2014 Edition version of that certification criterion) is aimed at significantly improving the market availability of electronic health information exchange services. Our proposed 2015 Edition ''view, download, transmit to 3rd party'' certification criterion includes a greater focus on enabling a patient to choose where they want to send their health information. We believe these proposed revisions would open new market opportunities for EPs, EHs, and CAHs to select best of breed products as well as reduce EHR technology developer burdens related to certification. Our proposals and requests for comment in this proposed rule also signal to the industry the future direction we hope to go in with our certification criteria and certification program. This advanced visibility can better assist EHR technology developers plan for the future.

TABLE 1—DISTRIBUTED TOTAL DEVELOPMENT AND PREPARATION COSTS FOR EHR TECHNOLOGY DEVELOPERS (2-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2014	50	9.82	46.63	28.23
2015	50	9.82	46.63	28.23
2-Year Totals		19.65	93.26	56.46

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange.

1. Standards, Implementation Specifications, and Certification Criteria

The HITECH Act established two new Federal advisory committees, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC) (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator for Health Information Technology (National Coordinator) on different aspects of standards, implementation specifications, and certification criteria. The HITPC is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria. Main

responsibilities of the HITSC include recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA titled ''Subsequent Standards Activity'' provides that the ''Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent'' with the schedule published by the HITSC. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITSC and endorsed by the National Coordinator, as well as other appropriate and necessary HIT standards, implementation specifications, and certification criteria. Throughout this process, the Secretary intends to continue to seek the insights and recommendations of the HITSC.

2. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the ''National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle'' (i.e., certification criteria adopted by the Secretary under section 3004 of the PHSA).

The certification program(s) must also ''include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act.'' Overall, section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HITSC, ''shall support the establishment of a conformance testing infrastructure, including the development of technical test beds.'' The HITECH Act also indicates that ''[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.''

B. Regulatory History

1. Standards, Implementation Specifications, and Certification Criteria Rules

The Secretary issued an interim final rule with request for comments titled, ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' (75 FR 2014, Jan. 13, 2010) (the ''S&CC January 2010 interim final rule''), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the S&CC January 2010 interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for meaningful use (MU) Stage 1 (formally titled: Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule, 75 FR 44590 (July 28, 2010) and referred to as the ''2011 Edition Final Rule''). The 2011 Edition Final Rule also established the first version of the Certified EHR Technology (CEHRT) definition. Subsequent to the 2011 Edition Final Rule (October 13, 2010), we issued an interim final rule with a request for comment to remove certain implementation specifications related to public health surveillance that had been previously adopted in the 2011 Edition Final Rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2011 Edition Final Rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of MU Stage 1 by EPs, EHs, and CAHs under the Medicare and Medicaid EHR Incentive Programs Stage 1 final rule (the ''EHR Incentive Programs Stage 1 final rule'') (see 75 FR 44314 for more information about MU and the Stage 1 requirements).

Subsequently, the Secretary issued a notice of proposed rulemaking with request for comments titled ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 13832, March 7, 2012) (the ''2014 Edition NPRM''), which proposed new and revised standards, implementation specifications, and certification criteria. After consideration of the public comments received on the 2014 Edition NPRM, a final rule was issued to adopt the 2014 Edition set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for MU Stage 2 as well as MU Stage 1 revisions (Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology; (77 FR 54163 Sept. 4, 2012) (the ''2014 Edition Final Rule''). On December 7, 2012, an interim final rule with a request for comment was jointly issued by ONC and CMS to update certain standards that had been previously adopted in the 2014 Edition final rule, as well as add an alternative measure for MU Stage 2, correct the regulation text, and modify the case number threshold exemption policy for clinical quality measure reporting under the EHR Incentive Program (77 FR 72985).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2014 Edition final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of MU Stage 2 by EPs, EHs, and CAHs under the Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (the ''EHR Incentive Programs Stage 2 final rule'') (see 77 FR 53968 for more information about the MU Stage 2 requirements).

On November 4th, 2013 the Secretary published an interim final rule with a request for comment, 2014 Edition Electronic Health Record Certification

Criteria: Revision to the Definition of ''Common Meaningful Use (MU) Data Set'' (78 FR 65884), to make a minor revision to the Common MU Data Set definition. This revision was intended to allow more flexibility with respect to the representation of dental procedures data for EHR technology testing and certification.

2. Medicare and Medicaid EHR Incentive Programs Rules

On January 13, 2010, CMS published the EHR Incentive Programs Stage 1 proposed rule (75 FR 1844). The rule proposed the criteria for Stage 1 of MU and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. Subsequently, CMS published a final rule (75 FR 44314) for the EHR Incentive Programs on July 28, 2010, simultaneously with the publication of the 2011 Edition Final Rule. The EHR Incentive Programs Stage 1 final rule established the objectives, associated measures, and other requirements that EPs, EHs, and CAHs must satisfy to demonstrate MU during Stage 1.

On March 7, 2012, CMS published the EHR Incentive Programs Stage 2 proposed rule (77 FR 13698). Subsequently, CMS published a final rule (77 FR 53968) for the EHR Incentive Programs on Sept. 4, 2012, simultaneously with the publication of the 2014 Edition final rule. The EHR Incentive Programs Stage 2 final rule established the objectives, associated measures, and other requirements that EPs, EHs, and CAHs must satisfy to demonstrate MU during Stage 2 as well as revised MU Stage 1.

As described above in Section II.B.1, ONC and CMS jointly issued an interim final rule with a request for comment on December 7, 2012 (77 FR 72985). The interim final rule updates certain standards that had been previously adopted in the 2014 Edition final rule, adds an alternative measure for MU Stage 2, corrects the regulation text, and modifies the case number threshold exemption policy for clinical quality measure reporting under the EHR Incentive Program.

3. ONC HIT Certification Program Rules

On March 10, 2010, ONC published a proposed rule (75 FR 11328) titled, ''Proposed Establishment of Certification Programs for Health Information Technology'' (the ''Certification Programs proposed rule''). The rule proposed both a temporary and permanent certification program for the purposes of testing and certifying HIT. It also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT. A final rule establishing the temporary certification program was published on June 24, 2010 (75 FR 36158) (the ''Temporary Certification Program final rule'') and a final rule establishing the permanent certification program was published on January 7, 2011 (76 FR 1262) (''the Permanent Certification Program final rule'').

On May 31, 2011, ONC published a proposed rule (76 FR 31272) titled ''Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes.'' The rule proposed a process for addressing instances where the ONC-Approved Accreditor (ONC–AA) engaged in improper conduct or did not perform its responsibilities under the permanent certification program, addressed the status of ONC-Authorized Certification Bodies in instances where there may be a change in the accreditation organization serving as the ONC–AA, and clarified the responsibilities of the new ONC–AA. All these proposals were finalized in a final rule published on November 25, 2011 (76 FR 72636).

The 2014 Edition Final Rule made changes to the permanent certification program. The final rule adopted a proposal to change the Permanent Certification Program's name to the ''ONC HIT Certification Program,'' revised the process for permitting the use of newer versions of ''minimum standard'' code sets, modified the certification processes ONC-Authorized Certification Bodies (ONC–ACBs) need to follow for certifying EHR Modules in a manner that provides clear implementation direction and compliance with the new certification criteria, and reduced regulatory burden by eliminating the certification requirement that every EHR Module be certified to the ''privacy and security'' certification criteria.

III. Provisions of the Proposed Rule Affecting Standards, Implementation Specifications, and Certification Criteria

A. 2015 Edition EHR Certification Criteria

General Context

This rule proposes new, revised, and unchanged certification criteria that would establish the technical capabilities and related standards and implementation specifications that could be implemented as part of an EP, EH, or CAH's CEHRT and their demonstration of either MU Stage 1 or MU Stage 2. We refer to these new, revised, and unchanged certification criteria as the ''2015 Edition EHR certification criteria'' or ''2015 Edition'' and propose to add this term and its definition to § 170.102. Additionally, we propose to codify the 2015 Edition EHR certification criteria in section 170.315 to set them apart and make it easier for stakeholders to quickly determine the certification criteria the 2015 Edition includes.

We discuss the new, revised, and unchanged certification criteria that we propose to adopt as the 2015 Edition EHR certification criteria below. We specify where the proposed certification criteria would be included in § 170.315. We also propose a substantive revision to the 2014 Edition syndromic surveillance certification criterion adopted at § 170.314(f)(3).

As we have in prior rulemakings, we include a table at the beginning of the discussion of each certification criterion or criteria that specifies the MU objective the proposed 2015 Edition EHR certification criterion or criteria supports. We also indicate in the table whether the criterion is ''eligible'' or ''ineligible'' for ''gap certification'' between the 2014 Edition and 2015 Edition under the ONC HIT Certification Program depending on whether it would be considered ''unchanged'' between editions. We provide accompanying rationale for the proposed certification criteria, including citing the recommendations of the HITPC and HITSC, where appropriate.

In contrast to our prior rulemakings, we discuss each certification criterion in the chronological order in which it would appear in the Code of Federal Regulations. In other words, the preamble that follows will discuss the proposed certification criteria in § 170.315(a) first, then § 170.315(b), and so on. This approach is designed to improve the preamble's readability and the ease with which commenters can reference back to sections of the proposed rule's preamble when necessary.

We propose, and readers should interpret, that the following terms used in proposed 2015 Edition EHR certification criteria have the same meanings we adopted in the 2014 Edition Final Rule (77 FR 54168–54169), in response to public comment: ''user,'' ''record,'' ''change,'' ''access,'' ''incorporate,'' ''create,'' ''transmit.'' Similarly, we propose that the scope of a 2015 Edition certification criterion is the same as the scope previously assigned to a 2014 Edition certification criterion (for further explanation, see the discussion at 77 FR 54168). That is,

certification to proposed 2015 Edition EHR certification criteria at § 170.315 would occur at the second paragraph level of the regulatory section and encompass all paragraph levels below the second paragraph level. We also propose to continue to use the same specific descriptions for the different types of ''data summaries'' established in the 2014 Edition Final Rule (77 FR 54170–54171) for the proposed 2015 Edition EHR certification criteria (i.e., ''export summary,'' ''transition of care/referral summary,'' ''ambulatory summary,'' ''inpatient summary,'' and ''clinical summary.''

Applicability—§ 170.300

Section 170.300 establishes the applicability of subpart C—Certification Criteria for Health Information Technology. We propose to revise paragraph (d) of § 170.300 to add in a reference to § 170.315, which would clarify which specific capabilities within a certification criterion included in § 170.315 have general applicability (i.e., apply to both ambulatory and inpatient settings) or apply only to an inpatient setting or an ambulatory setting.

• *Computerized Provider Order Entry*

Section 3000 of the Public Health Service Act, as added by section 13101 of the HITECH Act, requires that computerized provider order entry (CPOE) capabilities be included in CEHRT. We included CPOE capabilities in the Base EHR definition, which is part of the CEHRT definition, under 45 CFR § 170.102. Within the 2011 and 2014 Editions, we adopted CPOE certification criteria that require EHR technology to be capable of performing CPOE for medication, laboratory, and radiology/imaging orders. Based on stakeholder feedback since the 2014 Edition Final Rule, we understand that this approach can prevent EHR technology developers from creating more efficient, provider-specific ''adaptations'' of EHR technology that support CPOE.[3] For example, a mobile adaptation of CPOE currently must include all of the capabilities listed in the 2014 Edition CPOE certification criterion (i.e., the adaptation must be capable of performing CPOE for each of the three types of orders (medication, laboratory and radiology/imaging)) even though the EHR technology developer's customers may only wish to use the mobile adaptation to enter medication orders away from the office.

Similarly, we can understand why our approach to CPOE certification can be interpreted by some providers as inconsistent with the flexibility provided in the FY/CY 2014 CEHRT definition under § 170.102. For example, the MU Stage 2 CPOE objective for EPs includes three associated measures (one measure for each of the three types of orders) and exclusions for each of those three measures. An EP who could potentially meet an exclusion for one or two of the measures would still need to possess EHR technology certified to the 2014 Edition CPOE certification criterion (that is, CEHRT that includes CPOE capabilities for each of the three types of orders). Additionally, the MU Stage 1 CPOE objective for EPs does not include measures for laboratory and radiology orders, which means EPs attempting this objective also do not necessarily require these additional certified CPOE capabilities. For these reasons, we propose for the 2015 Edition to split the ''computerized provider order entry'' certification criterion into three separate certification criteria with each criterion focused on one of the three order types. Certification criteria focused on each order type would permit EHR technology developers to develop order-specific CPOE adaptations and provide EPs, EHs, and CAHs with significantly more implementation flexibility. If an EP expects to meet the MU exclusion for one or two of the MU measures (i.e., writing fewer than 100 of each order type during an EHR reporting period), they could choose to adopt EHR technology certified only to the 2015 Edition CPOE certification criterion for the order types reflected in the measure(s) they expect to demonstrate for MU. This approach would permit an EP to meet the Base EHR definition requirements and CEHRT definition without having to adopt EHR technology that includes certified CPOE capabilities they would not expect to use for MU.

We caution, however, that the additional flexibility that this proposed approach enables also comes with potential risk for EPs who expect to qualify for one or more of the exclusions from the CPOE measures discussed above, but do not ultimately satisfy the exclusion criteria based on the number of orders written during an EHR reporting period. EPs who choose to possess EHR technology that is not certified for each of the three types of orders may risk not having EHR technology that meets the CEHRT definition if they ultimately fail to meet one or more MU exclusions. In most cases, we expect that EPs' scope of practice and the MU measures they need to meet will inform their decision (and corresponding responsibility) to adopt EHR technology certified to the now separately proposed CPOE capabilities. For example, a chiropractor may never or rarely place medication and laboratory orders and, thus, would not necessarily need EHR technology certified to the specific proposed CPOE certification criteria for those order capabilities. Conversely, an EP practicing obstetrics and gynecology may need EHR technology certified for all three CPOE order types. Overall, we emphasize that EHR technology developers need to be aware that this additional certification flexibility and subsequent certification decisions could have corresponding impacts on EPs who are ultimately responsible for ensuring that their EHR technology meets the CEHRT definition.

The 2015 Edition ''CPOE'' certification criteria omit the ''at a minimum'' language included in the 2014 Edition and 2011 Edition CPOE certification criteria. This language was included in prior editions to indicate that EHR technology developers could include capabilities that support other types of orders. We believe this language is extraneous because we have consistently maintained that certification criteria (and certification in general) serve as minimum requirements or a baseline. As has always been the case, EHR technology developers may include capabilities in their EHR technology that go beyond all certification requirements.

• *Computerized Provider Order Entry—Medications*

MU Objective

Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

§ 170.315(a)(1) (Computerized physician order entry—medications).

Gap Certification Status

Eligible.

As discussed above, we propose to adopt a 2015 Edition CPOE certification criterion specific to medication ordering. This proposed criterion is structured substantially similar to the 2014 Edition version, except it does not reference laboratory and radiology/imaging orders.

[3] Please see 77 FR 54267–68 for a discussion of adaptations.

• *Computerized Provider Order Entry—Laboratory*

MU Objective

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

§ 170.315(a)(2) (Computerized physician order entry—laboratory).

Gap Certification Status

Ineligible.

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 amended the Public Health Service Act and revised the federal program for certification and oversight of clinical laboratory testing. CLIA applies to all clinical laboratories in the United States (in addition to some international laboratories that receive specimens from the United States for specialized testing not available in the United States) that perform examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. Certain CLIA requirements focus on the communication and receipt of test orders (under pre-analytic systems) and test results (under post-analytic systems) between an ordering provider and a clinical laboratory. Since the implementing regulations for CLIA were established at a time when paper was the dominant method of communication for laboratory orders and results (test requisitions and patient reports), the CLIA regulations governing these activities require each laboratory to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct identified problems.

As electronic methods for ordering and reporting clinical laboratory information become more prevalent and commonplace it is important to ensure that the intent of the CLIA regulations can be fully supported by EHR technology. This is especially important with regard to patient safety, the accurate, reliable ordering of clinical laboratory testing, and the accurate, reliable, and timely reporting of clinical laboratory test results. In light of the accelerating movement toward the electronic exchange of clinical information (including the transmission of laboratory orders and results), CMS issued guidance [4] to clarify specific sections of the CLIA regulations. This guidance specified that clinical laboratories should test and verify the accuracy and reliability of each interface to an EHR technology. Since there are thousands of EHR technologies implemented across provider organizations and each likely has more than one laboratory interface, the task of testing both orders and reporting interfaces can be expensive, labor intensive, and time consuming. Additionally, CLIA requires periodic review of these interfaces so this is not a one-time procedure.

As a step toward addressing these issues, we propose to expand (compared to the 2014 Edition versions) the 2015 Edition certification criteria focused on the exchange of laboratory orders and results (§§ 170.315(a)(2) and (b)(4) and (5)). These revised 2015 Edition certification criteria propose certain CLIA-specific requirements and include updated laboratory exchange standards. CLIA-specific requirements have been included in the ''electronic incorporation of lab results'' standard at § 170.205(j)(2) and the ''laboratory orders'' standard at § 170.205(l)(1) and we reference these standards in the appropriate proposed certification criteria. Inclusion of CLIA-specific requirements and updated standards will allow for a more comprehensive evaluation of EHR technology's capabilities in regards to supporting compliance with the CLIA regulations. We believe, upon adoption of the 2015 Edition, it would be possible for CMS to issue additional guidance to further clarify how CLIA requirements related to ongoing interface testing could be met if EHR technology were to be certified to these more comprehensive 2015 Edition certification criteria. Accordingly, we propose a ''CPOE—laboratory'' certification criterion as well as ''incorporate laboratory tests and values/results,'' and ''transmission of electronic laboratory tests and values/results to ambulatory providers'' certification criteria (discussed later in this preamble) to include more comprehensive capabilities focused on ensuring EHR technology's ability to perform capabilities consistent with corresponding CLIA regulatory requirements.

For the 2015 Edition ''CPOE—laboratory'' certification criterion, we propose to adopt, for the ambulatory setting, the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1–US Realm, Draft Standard for Trial Use, November 2013 (S&I Framework LOI).[5] Due to the absence of a consensus standard for the purpose of sending laboratory orders from EHRs to labs, this standard was developed in conjunction with laboratories representative of the industry, EHR technology developers, and provider stakeholders through an open consensus-based process under the Standards and Interoperability Framework (S&I Framework) and was balloted and approved through HL7, a standards development organization. We propose to adopt the S&I Framework LOI standard at § 170.205(l)(1). We also propose to require the use of, at a minimum, the version of Logical Observation Identifiers Names and Codes (LOINC®) adopted at § 170.207(c)(2) (version 2.40) as the vocabulary standard for laboratory orders. Last, we propose that laboratory orders must include all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8). The use of these standards and compliance with these requirements should greatly improve the interoperability of laboratory orders sent from ambulatory EHR technology to a laboratory and laboratory compliance with CLIA.

• *Computerized Provider Order Entry—Radiology/Imaging*

MU Objective

Use CPOE for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.

2015 Edition EHR Certification Criterion

§ 170.315(a)(3) (Computerized physician order entry—radiology/imaging).

Gap Certification Status

Eligible.

As discussed above, we propose to adopt a 2015 Edition CPOE certification criterion specific to radiology/imaging ordering. This proposed criterion is structured substantially similar to the 2014 Edition version, except it does not reference laboratory and medication orders.

• *Drug-Drug, Drug-Allergy Interaction Checks*

MU Objective

Implement drug-drug and drug-allergy interaction checks.

2015 Edition EHR Certification Criterion

[4] *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter10-12.pdf.*

[5] *http://www.hl7.org/special/committees/projman/searchableprojectindex.cfm?action=edit&ProjectNumber=922.*

§ 170.315(a)(4) (Drug-drug, drug-allergy interaction checks).

Gap Certification Status

Eligible.

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. However, we do solicit public comment on several related issues.

The 2014 Edition Drug-Drug, Drug-Allergy Interaction Checks certification criterion (45 CFR 170.314(a)(2)) requires EHR technology to be able to automatically and electronically indicate to a user any drug-drug and drug-allergy contraindications (''DDI/DAI''), where such contraindications are based on a patient's medication list and medication allergy list. The criterion further requires that such checks occur before a medication order is completed and acted upon during computerized provider order entry (CPOE). The criterion also requires that EHR technology certified to this criterion be able to adjust severity levels for drug-drug interaction checks and that such ability be limited to an identified set of users or available as a system administrative function.

Because DDI/DAI checks are intended to identify potential medical errors before they occur, these checks can be valuable tools for improving patient safety and for improving overall health outcomes. In order for DDI/DAI checks to be effective, however, action must be taken in response to a notification. When health care providers ignore a notification for DDI/DAI, the very benefit that such checks provide is eliminated.

Given the positive impact we believe DDI/DAI checks can have on patient safety, we are considering whether a future certification criterion edition could require DDI/DAI capable EHR technology to track user responses to DDI/DAI notifications (''response tracking'') and whether commenters believe this would be a positive potential step toward improving user experience with DDI/DAI checking. The purpose of including this type of capability in a certification criterion would be to equip health care providers with response data that they could use to improve their own performance and the safe use of their EHR technology. With such response tracking data, health professionals could analyze the notifications that are often ignored or missed and could work with clinicians to learn why they ignored or missed them. Understanding clinician decisions related to DDI/DAI notifications also can help health professionals make such notifications more effective, and potentially eliminate ineffective notification methods. This information also may be helpful for EHR technology developers as they design DDI/DAI checks and notifications.

We therefore seek comment on whether we should consider adopting a certification criterion as part of a future edition of certification criteria that would require EHR technology to be able to track health professionals' responses to the DDI/DAI checks that are performed and whether such a capability should track if and when the health professional viewed, accepted, declined, ignored, overrode, or otherwise commented on the product of a DDI/DAI check. We also seek comment on who should be permitted to review the data collected by the DDI/DAI check tracking capability, who should be able to adjust its configuration settings, whether the data tracked should be limited in scope or specificity, and whether EHR technology should be able to track when an adverse event occurs for which a DDI/DAI check was missed or ignored.

Last, we seek comment on whether a DDI/DAI tracking capability should only track inaction or responses related to certain drug-drug and drug-allergy reactions, such as only tracking DDI/DAI alerts that if missed or ignored would cause severe reactions in patients. We also seek comment on what factors, definitions, standards, or existing consensus should be considered in determining whether a likely DDI/DAI reaction should be considered severe.

• *Demographics*

MU Objective

Record the following demographics: preferred language; sex; race; ethnicity; date of birth; and for the inpatient setting only, date and preliminary cause of death in the event of mortality in the EH or CAH.

2015 Edition EHR Certification Criterion

§ 170.315(a)(5) (Demographics)

Gap Certification Status

Ineligible.

We propose to adopt a 2015 Edition ''demographics'' certification criterion that revises the 2014 Edition version. Our two proposals for the 2015 Edition criterion address a new standard for recording preferred language and that EHR technology must be capable of enabling a user to electronically record, change, and access the date of death and the preliminary cause of death.

Preliminary Cause of Death and Date of Death

We propose to include in the 2015 Edition the capability to enable a user to electronically record, change, and access the ''date of death'' as a required capability that EHR technology designed for the inpatient setting must demonstrate. We previously included this capability as part of the 2011 Edition ''demographics'' certification criterion and inadvertently omitted it from the 2014 Edition. Thus, this change would more accurately track the data required by the meaningful use criteria. To note, this functionality would be in addition to the inclusion in the 2015 Edition ''demographics'' certification criterion of the same capability to enable a user to electronically record, change, and access ''preliminary cause of death'' in case of mortality as is included in the 2014 Edition ''demographics'' certification criterion.

Preferred Language

Based on specific HITSC recommendations, we adopted ISO 639–2 constrained by ISO 639–1 for recording preferred language in the 2014 Edition ''demographics'' certification criterion. More specifically, this means that EHR technology is required to be capable of using the alpha-3 codes of ISO 639–2 to represent the corresponding alpha-2 code in ISO–639–1. To provide further clarity, we issued FAQ 27 [6] in which we stated that where both a bibliographic code and terminology code are present for a required ISO 639–2 language, EHR technology is expected to be capable of representing the language in accordance with the (T) terminology codes (ISO 639–2/T) for the purposes of certification.

After we issued FAQ 27, we issued FAQ 43 [7] in which we acknowledge that our constrained approach to the use of ISO 639–2 unintentionally excluded multiple languages that are currently in use, such as sign language and Hmong. Additionally, ISO 639–2 is meant to support written languages, which may not be the language with which patients instinctively respond when asked for their preferred language. To improve this situation, we propose to adopt one of the following three options for the 2015 Edition ''demographics'' certification criterion:

[6] *http://www.healthit.gov/policy-researchers-implementers/27-question-10-12-027.*

[7] *http://www.healthit.gov/policy-researchers-implementers/43-question-11-13-043.*

Option 1: Adopt ISO 639–2 [8] codes—in full—as part of certification to the 2015 Edition ''demographics'' certification criterion. We note, however, that as mentioned in FAQ 43, the ISO–639–2 standard was ''intended for written languages primarily.'' For instance, ''Chinese'' is represented by its official language, Mandarin, in the code list. This would not account for the commonly spoken Cantonese language/dialect or other spoken Chinese languages/dialects. As a result, EHR technology developers may find that particular spoken languages are not in all cases sufficiently supported by the constrained standard we adopted for 2014 Edition certification. We have proposed this option in our regulatory text and propose to adopt the full ISO–639–2 codes at § 170.207(g)(2). Note, to implement this proposal, we would have to modify the regulatory text hierarchy in § 170.207(g) to designate the standard referenced by the 2014 Edition version of this certification criterion at § 170.207(g) to be at § 170.207(g)(1).

Option 2: Adopt ISO 639–3.[9] We chose not to adopt ISO 639–3 as part of the 2014 Edition ''demographics'' certification criterion in response to one comment on our proposed 2014 Edition criterion because we believed it exceeded the baseline necessary for certification and we had insufficient stakeholder feedback. ISO 639–3 is a code set that aims to define three-letter identifiers for all known human languages. ISO 639–3 attempts to provide as complete an enumeration of languages as possible, including living, extinct, ancient, and constructed languages, whether major or minor, written or unwritten. We seek comment on its appropriateness as the baseline standard for recording preferred language as part of the 2015 Edition ''demographics'' certification criterion.

Option 3: Adopt Request for Comments (RFC) 5646.[10] RFC 5646 entitled ''Tags for Identifying Languages, September 2009'' is the coding system that is commonly used to encode languages on the web and is the most current RFC for this purpose and listed as a ''best current practice.'' The first part of the code relies on the shortest ISO–639 code for the language. That means a 2-character code if the language is specified in ISO 639–1 or a 3-character code from ISO 639–2 or –3, if the language is only listed in one of those two ISO codes. We are also aware that RFC 5646 supports dialects.

We welcome comments on which standard should be required for recording preferred language as part of the 2015 Edition ''demographics'' certification criterion. Additionally, we propose in a later section of this rule that the chosen standard would also become the preferred language standard for the ''Common MU Data Set'' definition. Please see section III.D.3 ''Common MU Data Set'' of this preamble for further discussion of this associated proposal.

• *Vital Signs, Body Mass Index, and Growth Charts*

MU Objective

Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0–20 years, including BMI.

2015 Edition EHR Certification Criterion

§ 170.315(a)(6) (Vital signs, body mass index, and growth charts)

Gap Certification Status

Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. However, we solicit public comment on the following issues. In the 2014 Edition Final Rule (77 FR 54203), we declined to revise the certification criterion at § 170.314(a)(4) in response to comments that recommended we require EHR technology to record vital signs in standardized vocabularies (e.g., LOINC, SNOMED CT, and UCUM). At the time, we believed that it was too complex and burdensome for technology developers to map workflows, templates, and forms used to capture vital signs to standardized vocabularies. We also expressed concern that such a requirement could cause EHR technology developers to map vital signs to a standardized terminology in one workflow but perhaps not others. We were concerned that such an approach could cause providers to be forced to use a given workflow, form, or template to achieve MU that is inconsistent with optimal workflow and usability. However, we noted that EHR technology developers would not be precluded from using standardized vocabularies to meet this 2014 Edition EHR certification criterion.

We have continued to receive stakeholder feedback that we should consider adopting standardized vocabularies for recording vital signs (e.g., LOINC for observations). However, we have also received feedback that we should continue to allow flexibility in how vital signs are recorded. As a result, we solicit comment on whether we should adopt standardized vocabularies for recording vital signs (specifically, whether we should adopt LOINC (for observations), SNOMED CT (for qualitative results), and UCUM (for units of measure)) in this certification criterion for the 2017 Edition. In addition to these vocabularies, we also solicit comment on whether other vocabularies would be better for recording vital signs.

In the 2014 Edition Final Rule, we stated that we intended to require that EHR technology be able to record all vital signs according to standardized technologies in the next EHR certification criteria edition (77 FR 54203). This was intended to be an incremental step toward interoperability at a more granular level. At the time of publication, we anticipated that the next certification criteria edition would be published with the MU Stage 3 rulemaking. However, given our modified approach to the rulemaking timeline discussed at the beginning of the preamble, we are using this intermediate 2015 Edition rulemaking to solicit more detailed comment on this issue to inform our policy decisions for the 2017 Edition.

For recording vital signs, we are considering two different approaches:

• *Option 1* would be to require that EHR technology be able to record vital signs data natively using the aforementioned standards as part of the vital signs certification criterion. For the majority of our 2014 Edition certification criteria, we only require vocabulary standard(s) be used as part of a transmission rather than natively within the EHR. While it is not the norm, we have already set precedent for certain 2014 Edition certification criteria (e.g., smoking status) to require EHR technology to demonstrate the ability to natively record data in a particular standard as opposed to only having to apply that standard when data is exchanged. One potential benefit of this approach is that the standardized vocabularies are applied to the data as it is collected (e.g., to provide contextual information about the data to assist with interpretation). A downside, however, is that it could require more upfront work on the part of providers to capture the data in a standardized way and that certain local approaches to data collection may need to be discontinued.

• *Option 2* would be to require that EHR technology be able to represent such data in the aforementioned standards in any certification criterion

[8] *http://www.loc.gov/standards/iso639-2/iso639-2ra.html*

[9] *http://www-01.sil.org/iso639–3/*

[10] *http://www.rfc-editor.org/info/rfc5646*

that references vital signs *when such data would be exchanged*. For example, when exchanging a summary care record, the EHR technology would need to ensure blood pressure is represented in the CCDA formatted summary care record in the appropriate standard. Presumably, this option would be less burdensome on providers. It would also continue to allow them to collect vitals in local and non-standardized ways within their own EHR technology. However, it could also result in lost precision regarding the context associated with the vitals recorded.

Last, additional feedback we have received from stakeholders indicated that if we were to pursue option 2, we would be best served to require EHR technology to record additional metadata related to the context around how the vital signs were collected. Stakeholders indicated that this additional information would provide context and comparability for the data if a standard vocabulary is not used when the data is recorded. For recording vitals, it is our understanding that unless particular contextual information associated with data collection is captured locally, data may be misinterpreted by a receiving party.

Without certain kinds of contextual information, vitals data cannot be cross-walked or coded correctly. For example, a single blood pressure measurement may not represent a patient's true blood pressure. In older patients, the American Heart Association (AHA) [11] recommends taking the patient's blood pressure twice while standing, recording the average of the two, and then taking the patient's blood pressure twice while sitting and using the sitting average as the final reading. The standing average is to be used as a reference point only. If this information (e.g., whether the patient was sitting or standing, if the measure is the first, second, or average) is not recorded in the EHR along with the blood pressure measurement itself, the readings may not be correctly understood by a receiving party, such as another provider or caregiver. Therefore, we are also soliciting comment on whether we should prioritize our attention toward making sure EHR technology can capture this kind of contextual information or other metadata and what kinds of data would be best or most helpful for EHR technology certification to require. Please note we are not proposing that blood pressure must be recorded according to the AHA's recommendations. Rather, we use their recommendations to illustrate how contextual information about vital signs may be important to prevent misinterpretation. Finally, we solicit comments on whether vocabularies (and other metadata) are sufficient for the reuse of more granular data elements and whether continued work through initiatives (e.g., the Clinical Information Modeling Initiative (CIMI), Fast Health Interoperable Resources (FHIR)) to support capturing clinical entity models or other approaches for representing more granular data elements is needed.

- Problem List

MU Objective
Maintain an up-to-date problem list of current and active diagnoses.
2015 Edition EHR Certification Criterion
§ 170.315(a)(7) (Problem list)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

- Medication List

MU Objective
Maintain active medication list.
2015 Edition EHR Certification Criterion
§ 170.315(a)(8) (Medication list)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition EHR certification criterion that is the same as the 2014 Edition version.

- Medication Allergy List

MU Objective
Maintain active medication allergy list.
2015 Edition EHR Certification Criterion
§ 170.315(a)(9) (Medication allergy list)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

- Clinical Decision Support

MU Objective
Use clinical decision support to improve performance on high-priority health conditions.
2015 Edition EHR Certification Criterion
§ 170.315(a)(10) (Clinical decision support)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion that revises the 2014 Edition version in several ways. The 2014 Edition EHR certification criterion for CDS (§ 170.314(a)(8)) requires EHR technology to perform certain capabilities based on ''demographics'' data. Since the 2014 Edition Final Rule's publication, we have received many clarifying questions on whether EHR technology presented for certification must demonstrate the capability to use more than one of the demographics data categories listed in the ''Demographics'' certification criterion adopted at § 170.314(a)(3). Similar to the proposed 2015 Edition ''Patient List Creation'' certification criterion's modification of the 2014 Edition version, we are also proposing to adopt a 2015 Edition CDS certification criterion that incorporates the guidance we provided in FAQ 39.[12] Specifically, the text of the 2015 Edition ''CDS'' certification criterion provides that EHR technology must demonstrate the capability to use at least one of the more specific data categories included in the ''demographics'' certification criterion (45 CFR 170.315(a)(5)) (e.g., sex or date of birth).

The 2014 Edition EHR certification criterion for CDS also requires EHR technology to provide Infobutton [13]-enabled diagnostic and therapeutic reference information (§ 170.314(a)(8)(ii)(2)) in accordance with one of the Infobutton implementation specifications at § 170.204(b)(1) or § 170.204(b)(2). Since the 2014 Edition Final Rule's publication, we received clarifying feedback that the Infobutton standard does not support vital signs and medication allergies data for linked referential CDS and subsequently issued FAQ 34 [14] to clarify how 2014 Edition testing and certification would handle this limitation.[15] As a result, we propose that the 2015 Edition CDS certification criterion will not require compliance with the Infobutton-enabled capability for vital signs nor medication allergies data. We also propose to discontinue referencing ''laboratory values/results'' data as we understand from stakeholder feedback that the Infobutton standard cannot support this specific data. Further, we propose to adopt the HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013 (at § 170.204(b)(3)) in

[11] New AHA Recommendations for Blood Pressure Measurement. *Am Fam Physician*. 2005 Oct 1;72(7):1391–1398.

[12] *http://www.healthit.gov/policy-researchers-implementers/39-question-04-13-039.*

[13] ''Infobutton'' is typically the shorthand name used to refer to the formal standard's name: HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton).

[14] *http://www.healthit.gov/policy-researchers-implementers/34-question-12-12-034.*

[15] *http://www.healthit.gov/policy-researchers-implementers/34-question-12-12-034.*

place of the older version referenced by the 2014 Edition certification criterion.

Health eDecisions Proposal

Launched in June 2012, an ONC Standards & Interoperability Framework initiative known as Health eDecisions (HeD) focused on defining and harmonizing standards that could facilitate the emergence of systems and services for shareable CDS. Since that time, the HeD Working Group has developed two use cases with functional requirements, defined and balloted relevant standards, developed IGs, and is in the process of conducting pilots and performing data collection for analysis.

HeD use case (UC) 1 defines the functional requirements needed to build a standard schema for the contents of three ''CDS Knowledge Artifact'' [16] types: event condition action (ECA) rules, order sets, and documentation templates.[17] UC 1 is based on the scenario of a ''CDS Knowledge Artifact supplier'' making a computable CDS Knowledge Artifact available to a ''CDS Artifact integrator.'' The HeD Working Group created the HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) (''HeD standard'') [18] as a companion document for the CDS Knowledge Artifact schema (described in the HeD standard IG). The HeD standard includes additional background, contextual information, and detailed documentation and guidance to support schema implementation.[19] Overall, implementation of the HeD standard would greatly assist the industry in producing and sharing machine readable files for representations of clinical guidance.

HeD UC 2 defines the interface requirements needed to send patient data and receive CDS guidance based on one scenario: a request for clinical guidance made to a CDS guidance supplier.[20] The HeD Working Group considered the following interactions with a CDS guidance supplier: drug dosing calculation; immunization forecasting; disease management; quality measure evaluation; transition of care support; prediction rule evaluation (e.g., APACHE score, AHRQ Pneumonia Severity Index); and severity of illness assessment (e.g., Charlson Index). The HeD Working Group created the HL7 Decision Support Service Implementation Guide, Release 1, Version 1 (December 2013) [21], which defines SOAP and REST Web service interfaces for CDS guidance services. The implementation of this IG would promote systems whereby a health care provider can send a question about a patient to a CDS guidance supplier and receive CDS guidance back in near real-time.

The functionality discussed above could significantly enhance the scalability and time to market of new clinical knowledge and improve care. We also believe, with the progress made by the HeD initiative since its launch, that this proposed rule serves as an opportunity to propose the HeD standard for testing and certification. Further, its proposal as part of the 2015 Edition permits EHR technology developers and other interested stakeholders to provide feedback on its readiness for inclusion in the 2017 Edition.

We therefore propose to adopt the HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) (''HeD standard'') as a standard at § 170.204(d) and to require that EHR technology be able to electronically process a CDS artifact formatted in the HeD standard. We also propose to adopt the HL7 Decision Support Service Implementation Guide, Release 1, Version 1 (December 2013) as a standard at § 170.204(e) and to require that EHR technology demonstrate the ability to make an information request, send patient data, and receive CDS guidance according to the interface requirements defined in the Decision Support Service IG. To supplement our proposals, we solicit comment on:

- What specifically ONC should focus on when it comes to testing and certification for acceptance and incorporation of CDS Knowledge Artifacts;
- The feasibility of implementing the interface requirements defined in the Decision Support Service IG to make an information request, send patient data, and receive CDS guidance in near real-time;
- The ease with which EHR technology could be developed to consume CDS Knowledge Artifacts;
- Whether we should work to distinguish between *complex* CDS Knowledge Artifacts and *simple* Knowledge Artifacts and to require only acceptance and incorporation of simple Knowledge Artifacts in the 2015 Edition, with increasing expectations of more complex capabilities in future editions;
- The ability to store and auto-configure a CDS Knowledge Artifact in EHR technology; and
- The ability to map the CDS Knowledge Artifact standard to data within the EHR technology (including medications, laboratory, and allergies information).

- Electronic Notes

MU Objective
Record electronic notes in patient records.
2015 Edition EHR Certification Criterion
§ 170.315(a)(11) (Electronic notes)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion that revises the 2014 Edition version. We propose a 2015 Edition ''electronic notes'' certification criterion that would include one new requirement compared to the 2014 Edition ''electronic notes'' certification criterion. Specifically, for the 2015 Edition certification criterion, we propose that EHR technology have the capability to search for information across separate notes within the EHR technology rather than just within one particular note. This expanded requirement is intended to reduce the time providers spend looking for specific patient information. The requirement to search across notes is *not limited to a specific method*. Instead, we are primarily concerned that the outcome expressed is demonstrated. We expect and encourage EHR technology developers to create innovative ways to achieve this functionality. As with the 2014 Edition ''electronic notes'' certification criterion, ''search'' continues to mean the ability to search free text and data fields of electronic notes.

While we propose to adopt the ''search across notes'' capability for the 2015 Edition, we request comment on the following:

- Whether this functionality should extend to all patient electronic notes stored in the EHR or just to a specific patient's electronic notes or specific types of patient notes;

[16] A CDS Knowledge Artifact is the encoding of structured CDS content as a rule to support clinical decision making in many areas of the health care system, including quality and utilization measures, disease outbreaks, comparative effectiveness analysis, efficacy of drug treatments, and monitoring health trends.

[17] HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) (''HeD standard'').

[18] *http://wiki.siframework.org/file/detail/implementation_guide_working_final_042413_lse_uploaded-1.docx.*

[19] Background documents and implementation guides can be found at *http://wiki.siframework.org/Health+eDecisions+Homepage.*

[20] HL7 Decision Support Service Implementation Guide, Release 1, Version 1 (December 2013).

[21] *http://wiki.siframework.org/file/view/20130830_DSS_IG_R1_for_201309_ballot.zip/448259852/20130830_DSS_IG_R1_for_201309_ballot.zip.*

• Whether we should require this functionality in the 2015 Edition or wait to include it in a potential 2017 Edition ''electronic notes'' certification criterion; and

• *Health care provider* opinions on whether the availability of such functionality (either searching across a specific patient's electronic notes stored in the EHR or all patients' electronic notes stored in an EHR) is so widespread that it would be unnecessary to require it as a condition of certification. We note that the ''electronic notes'' objective and measure for MU Stage 2 requires that notes be text searchable, but does not require searching across electronic notes.

• Whether additional metadata should be required as part of electronic notes (such as the HL7 R2 header) to assist in both searching of notes, but also to make exporting electronic notes for patient data portability easier.

• Drug Formulary Checks

MU Objective
Implement drug formulary checks.
2015 Edition EHR Certification Criterion
§ 170.315(a)(12) (Drug formulary checks)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. However, we solicit public comment on the following issues. In the 2014 Edition EHR certification criteria final rule, we strongly encouraged EHR technology developers to use the updated Medicare Part D e-prescribing standards, including a new version of the NCPDP Formulary and Benefit standard (NCPDP Formulary and Benefit Standard 3.0), if or when it was finalized as an official Part D E-Prescribing standard (77 FR 45022). At the time, we did not believe it was necessary to require the use of the NCPDP Formulary and Benefit Standard 3.0 if/when it became the official Part D E-Prescribing standard as a condition of certification because our certification criterion was flexible and permitted EHR technology to access and store external drug formularies in support of meaningful use.

CMS agreed with comments on the CY 2013 Physician Fee Schedule proposed rule that suggested the adoption of the NCPDP Formulary and Benefit Standard 3.0 as the official Part D E-Prescribing standard should be delayed until after July 1, 2014, which was expected to be the ''sunset date'' when NCPDP would cease to support version 1.0 (77 FR 68892). Furthermore, CMS determined that it should also delay recognition of the NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits Standard 1.0 because it did not believe that two versions of a standard should be used over an extended period of time (77 FR 68892). Having come within a year of the originally proposed sunset date, CMS recently re-proposed and finalized a proposal to recognize NCPDP Formulary and Benefit Standard v.3.0 as a backward compatible version of NCPDP Formulary and Benefit Standard 1.0 for the period of July 1, 2014 through February 28, 2015, and to retire version 1.0 and adopt version 3.0 as the official Part D E-Prescribing standard on March 1, 2015 (77 FR 74787–74789).[22]

The NCPDP Formulary and Benefit Standard 3.0 includes updates based on industry feedback and new or modified business needs. For a full discussion of the changes that were made to previous versions of the NCPDP Formulary and Benefit Standard that NCPDP ultimately developed toward NCPDP Formulary and Benefit Standard 3.0, see 77 FR 45023–45024).

The HITSC has discussed the current structure of the NCPDP Formulary and Benefit Standard v.4.0[23] and has noted potential limitations. These include:[24]

• That large files are needed to provide the formulary and benefit data;

• that the data are submitted in batch rather than in real-time;

• the provider cannot see patient-specific variations in drug-specific benefits;

• an assumption that the patient's current drug plan is identified through a successful eligibility check based on a five-point identifier rather than the actual pharmacy data;

• the inability to detect differences in primary and secondary prescription benefit coverage;

• that the provider must manually pull updated formulary and benefit data rather than being pushed the updates.

In order to resolve the limitations of NCPDP Formulary and Benefit Standard v.4.0, the HITSC has discussed that a new or updated standard or transaction is needed for EHRs to develop the functionality to run patient-specific formulary checks against the patient's actual drug benefit for a specific drug and dose in a timely manner. However, this is a long-term potential suggestion. Despite the NCPDP Formulary and Benefit Standard v.4.0's limitations, it does support providers' ability to know what drugs are included in the formulary, which can assist them in helping patients make decisions about their care. In the meantime, the NCPDP Formulary and Benefit Standard v.3.0 appears to be the best standard available for this particular use case. As described above, CMS has recently finalized a proposal to recognize NCPDP Formulary and Benefit Standard v.3.0 as a backward compatible version of NCPDP Formulary and Benefit Standard 1.0 starting on July 1, 2014, and v.4.0 includes minor changes compared to v.3.0.

For a long-term potential solution, the NCPDP Telecommunications Standard used for pharmacy-to-payer transactions may offer some solutions when used in conjunction with the NCPDP Formulary and Benefit Standard v.4.0, specifically for certifying patient-level eligibility and prescription drug benefits with detailed information defining reimbursement or denial of compensation with explanations. However, to date, the NCPDP Telecommunications Standard has been used mostly for real-time billing of pharmacy transactions.

In light of these circumstances and challenges, we solicit comment on whether we should leave this certification criterion as-is (in its flexible form) as we consider 2017 Edition policy or if it would be advantageous for us to adopt a standard in this 2015 Edition certification criterion for which compliance would be required. We also solicit comment on:

• The appropriateness of using the NCPDP Telecommunications Standard in conjunction with the NCPDP Formulary and Benefit Standard v.3.0 or v.4.0 to support expanded use cases such as real-time benefit checks; and

• Whether there are other standards or solutions that can address the potential limitations identified by HITSC and the use case of real-time benefit checks.

• Smoking Status

MU Objective
Record smoking status for patients 13 years old or older.
2015 Edition EHR Certification Criterion

[22] CMS originally proposed retiring V1.0 on July 1, 2014, but subsequently decided to postpone the retirement date to March 1, 2015, in response to comments to allow the industry adequate time to implement the necessary changes and testing to implement v3.0 (78 FR 74789).

[23] V.4.0 has minor changes compared to v.3.0, including removal of values from an unused diagnosis code, typographical changes, and a change to the standard length of the name field. CMS has proposed adopting v.3.0 (CY2014 Physician Fee Schedule proposed rule), which includes the substantive changes from previous versions.

[24] Clinical Operations Workgroup Update to the HITSC on June 19, 2013. *http://www.healthit.gov/FACAS/sites/faca/files/clinical_operations_wg_update_062013_0.pdf.*

§ 170.315(a)(13) (Smoking status)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Image Results

MU Objective
Imaging results and information are accessible through Certified EHR Technology.
2015 Edition EHR Certification Criterion
§ 170.315(a)(14) (Image results)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Family Health History

MU Objective
Record patient family health history as structured data.
2015 Edition EHR Certification Criterion
§ 170.315(a)(15) (Family health history)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion that revises the 2014 Edition version. The 2014 Edition ''family health history'' certification criterion requires EHR technology to demonstrate that it is capable of enabling a user to electronically record, change, and access a patient's family health history according to certain standards. In support of the MU Stage 2 requirement that family health history be captured in structured data, we adopted two standards for recording family health history: Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT®) terms for familial conditions and the HL7 Pedigree standard. In adopting SNOMED CT®, we acknowledged that HL7 Pedigree was a relatively new standard and that an implementation guide had not yet been published.[25] As such, we stated that the use of SNOMED CT® was perhaps the best intermediate step for coding family health history in structured data if one was not to use the HL7 Pedigree standard.[26]

In April 2013, an HL7 Pedigree IG, HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1,[27] was published. With the publication of this IG, we propose to adopt a 2015 Edition ''family health history'' certification criterion that requires solely the recording of family health history according to the HL7 Pedigree standard and the HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1 (i.e., it omits SNOMED CT® as an option). We believe that convergence to this single standard and IG will ensure more precise electronic recording of family health history data and, more importantly, improve the interoperability of family health history information. As part of the 2014 Edition Final Rule, we incorrectly assigned the HL7 Pedigree standard to § 170.207 where we adopt ''vocabulary'' standards. Accordingly, for the 2015 Edition proposal we have placed the HL7 Pedigree standard and its IG in § 170.205(m)(1) to more accurately place it in the ''content'' exchange standards section.

• Patient List Creation

MU Objective
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.
2015 Edition EHR Certification Criterion
§ 170.315(a)(16) (Patient list creation)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition ''patient list creation'' certification criterion that revises the 2014 Edition version to incorporate our guidance provided in FAQ 39.[28] Specifically, the text of the 2015 Edition ''patient list creation'' certification criterion provides that EHR technology must demonstrate its capability to use at least one of the more specific data categories included in the ''demographics'' certification criterion (45 CFR 170.315(a)(5)) (e.g., sex or date of birth).

For a potential 2017 Edition ''patient list creation'' certification criterion, we request comment on four issues for EHR technology certification:

(1) Whether patient communication preferences should be a requirement for the inpatient setting;

(2) Whether a minimum list of patient communication preferences should be more specifically defined in order to require that EHR technology be capable of creating patient reminder lists based on a patient's preferred communication medium (e.g., electronically through secure email or a patient portal, paper/regular mail, or phone);

(3) Whether EHR technology should be able to use a patient's preferred language as a filter; and

(4) Because this certification criterion also supports the meaningful use objective and measure related to ''patient reminders,'' whether we should include within this certification criterion or adopt a new certification criterion that would require EHR technology be able to provide patient reminders according to identified patient preferences and preferred language (for example, if the patient preference for a reminder was ''email'' and preferred language was English, the EHR technology would have to demonstrate that it could send reminders in English via email).

• Patient-Specific Education Resources

MU Objective
Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.
2015 Edition EHR Certification Criterion
§ 170.315(a)(17) (Patient-specific education resources)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition ''patient-specific education resources'' certification criterion that revises the 2014 Edition version in three ways. Our first proposal is to adopt this certification without the requirement that EHR technology be capable of electronically identifying patient-specific education resources based on ''laboratory values/results.'' We understand from stakeholder feedback on the 2014 Edition version of this criterion that the Infobutton standard cannot support this level of data specificity, and we do not expect EHR technology developers to develop an alternative method that could electronically identify patient-specific education resources based on laboratory values/results. Our second proposal is to adopt the HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013. This is the updated IG of the Draft Standard for Trial Use (DSTU) version we adopted for the 2014 Edition ''patient-specific education resources'' certification criterion. To clearly distinguish this IG in the regulation text from the DSTU version, we propose a technical amendment to § 170.204(b)(2) to note that the version is the DSTU version. Finally, our third proposal is to revise the regulation text to be more consistent with the intent and interpretation of the 2014 Edition certification criterion regulation text we expressed in the 2014

[25] 77 FR 54174 (September 4, 2012).

[26] 77 FR 54174 (September 4, 2012).

[27] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=301.*

[28] *http://www.healthit.gov/policy-researchers-implementers/39-question-04-13-039.*

Edition final rule.[29] The text of the 2015 Edition certification criterion makes clear that the EHR technology must demonstrate the capability to electronically identify patient-specific education resources using Infobutton and an alternative method that does not rely on Infobutton. To note, we propose that the guidance we provided in FAQ 40[30] would still be applicable to the 2015 Edition ''patient-specific education resources'' certification criterion.

We request comment on whether we should adopt a different approach related to the methods EHR technology uses to electronically identify patient-specific education resources for the 2015 Edition, a potential 2017 Edition ''patient-specific education resources'' certification criterion, or both. The 2014 Edition and the proposed 2015 Edition EHR certification criteria require EHR technology to demonstrate the capability to electronically identify for a user patient-specific education resources using Infobutton *and an alternative method.* We seek comment on whether we should: (1) Maintain this approach; (2) require EHR technology to demonstrate only the use of Infobutton, but permit EHR technology to be certified to other methods upon an EHR technology developer's request for the purpose of an EP, EH, or CAH being able to use the alternative certified method for MU (to count such use toward meeting the measure); or (3) certify only the use of Infobutton and consult with CMS regarding a meaningful use policy change that would permit the use of any method (certified or not) to electronically identify patient-specific education resources, provided that the EP, EH, or CAH has EHR technology certified to perform the Infobutton capability.

We also seek comment on whether we should require that EHR technology be capable of providing patient-specific education resources in a patient's preferred language in the 2015 Edition, in a potential 2017 Edition certification criterion, or in both.

• Electronic Medication Administration Record

MU Objective
Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

2015 Edition EHR Certification Criterion
§ 170.315(a)(18) (Inpatient setting only—electronic medication administration record)

Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Advance Directives

MU Objective
Record whether a patient 65 years old or older has an advance directive.

2015 Edition EHR Certification Criterion
§ 170.315(a)(19) (Inpatient setting only—advance directives)

Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Implantable Device List

MU Objective
N/A

2015 Edition EHR Certification Criterion
§ 170.315(a)(20) (Implantable Device List)

Gap Certification Status
Ineligible

We propose to adopt a new 2015 Edition certification criterion that would require EHR technology to be able to record and display a unique device identifier (UDI)[31] and other information about a patient's implantable devices. This proposed certification criterion represents a first step towards enabling EHR technology to facilitate the widespread capture and use of UDI data to prevent device-related medical errors, improve the ability of hospitals and clinicians to respond to device recalls and device-related patient safety information, and achieve other important patient safety and public health benefits consistent with the fundamental aims of the HITECH Act[32] and the July 2, 2013 HHS Health Information Technology Patient Safety Action and Surveillance Plan.[33]

FDA issued the Unique Device Identification System Final Rule on September 24, 2013.[34] This FDA rule implements a statutory directive to establish a ''unique device identification system'' for medical devices that will enable adequate identification of devices through distribution and use.[35] It accomplishes this objective by requiring that a UDI be included on the label of most medical devices distributed in the United States. In addition, for each device with a UDI, a standard set of identifying elements will be publicly available through the FDA's Global Unique Device Identification Database (GUDID).[36] FDA is scheduled to fully implement the UDI system for devices that are implantable, life-saving, and life sustaining by September 2015.[37]

We believe that EHR technology will play a key role in the widespread adoption and utilization of UDIs and that its use of UDIs can help reduce device-related medical errors and provide other significant patient safety, health care quality, and public health benefits. Specifically, EHR technology could be leveraged in conjunction with automated identification and data capture (AIDC) technology or other technologies to streamline the capture and exchange of UDIs and associated device data in clinical and administrative workflows. Moreover, patients' UDI data in EHR technology could pave the way for new CDS and help health care providers more rapidly and accurately identify a patient's devices and key information about the safe and effective use of such devices. Further, EHR technology could facilitate better and more accurate reporting of adverse events and other information to reporting systems and registries and

[29] 77 FR 54216

[30] *http://www.healthit.gov/policy-researchers-implementers/40-question-04-13-040.*

[31] A UDI is a unique numeric or alphanumeric code that consists of two parts: (1) A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and (2) a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: The lot or batch number within which a device was manufactured; the serial number of a specific device; the expiration date of a specific device; the date a specific device was manufactured; the distinct identification code required by 21 CFR § 1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/.*

[32] Specifically, the certification criteria supports the National Coordinator's responsibility under the HITECH Act to ensure that the nation's health IT infrastructure supports activities that ''reduce[] medical errors,'' ''improve[] health care quality,'' ''improve[] public health activities,'' and ''facilitate[] the early identification and rapid response to public health threats and emergencies . . . .'' 42 U.S.C. § 300jj–11(b)(2) & (7).

[33] Available at *http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety.* The first objective of the Health IT Patient Safety Plan is to ''use health IT to make care safer.'' *See id.* at 7. The Plan specifically contemplates that ONC will update its standards and certification criteria to improve safety-related capabilities and add new capabilities that enhance patient safety.

[34] 78 FR 58786.

[35] 21 U.S.C. § 360i(f).

[36] The FDA's draft guidance on the GUDID is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/.*

[37] Pursuant to 21 U.S.C. § 360i(f), FDA must implement the Unique Device Identification System Final Rule with respect to devices that are implantable, life-saving, and life sustaining not later than two years after the rule was finalized. Other implementation and compliance dates are detailed in the final rule.

enable more effective corrective and preventative action in response to device recalls and alerts and other device-related information related to patient safety.[38]

We recognize that additional standards and technical specifications will be required to support the full range of capabilities contemplated above. Indeed, efforts to identify or develop these standards are already underway.[39] Nevertheless, we believe that it is both feasible and important for EHR technology developers to begin implementing at least the baseline functionality necessary to capture, store, and retrieve UDIs and other contextually relevant information associated with a patient's medical devices, specifically implantable devices. By their nature, these devices cannot be inspected with the naked eye and are more susceptible to misidentification, which can result in patient harm. Moreover, once a device is implanted, it is separated from its UDI, which is attached only to the device's labeling and not directly marked on the device itself. Under the FDA's accelerated implementation timeline, UDIs will be available for all implantable devices no later than September 2015.

We propose to adopt a 2015 Edition certification criterion focused on EHR technology's ability to record UDI information about implantable devices. More specifically, EHR technology would have to enable a user to electronically record the UDI of an implantable device and other relevant information (such as a procedure note or additional information about the device) as part of a patient's ''implantable device list.'' EHR technology would also be required to allow a user to electronically access and view a patient's list of UDIs and other relevant information associated with a patient's implantable devices. In addition, the EHR technology would need to be able to parse the UDI in order to extract and allow a user to view the ''device identifier'' and ''production identifier'' portions of the UDI. The purpose of this requirement is to ensure that a user will be able to use the device identifier to manually retrieve associated data elements from an authoritative source based on the GUDID, once available and, similarly, to ensure that a user will be able to manually use the production identifier in the event of a device recall. We expect that EHR technology would be able to automate these processes once appropriate standards and technical specifications are developed.

As previously indicated, we believe EHR technology should also facilitate the UDI's exchange in order to increase the overall availability and reliability of information about patients' implants and other devices. Thus, we propose to reference ''the UDI(s) for a patient's implantable device(s)'' in the following proposed 2015 Edition EHR certification criteria which also propose the adoption of the newest version of the Consolidated CDA.[40] We understand that this data can already be accommodated in the current Consolidated CDA version and is best placed in the ''Product Instance'' data element which is part of the Procedures template (see section 5.65 of the current Consolidated CDA version adopted at 45 CFR 170.205(a)(3) and incorporated by reference at 45 CFR 170.299(f)(8)). We seek comment from Consolidated CDA experts on whether there is a better location to place this information so that we may provide updated guidance in a final rule or FAQ. For clarity and context purposes each impacted proposed certification criterion will include a reminder about our proposal here. However, to reduce redundancy, this proposal and its rationale serves as the basis for the UDI's inclusion in each of those criteria.

- 170.315(b)(1)—Transitions of care.
- 170.315(b)(6)—Data portability.
- 170.315(e)(1)—View, download, and transmit to third party.
- 170.315(e)(2)—Clinical summary.

We have also proposed elsewhere in this Proposed Rule to modify § 170.102 to include new definitions for ''implantable device,'' ''unique device identifier,'' ''device identifier,'' and ''production identifier.'' This will prevent any interpretation ambiguity and ensure that each term's specific meaning reflects the same meaning given to them in the Unique Device Identification System Final Rule and in 21 CFR 801.3.

We seek public comment on additional EHR technology capabilities we are considering including as part of the 2017 Edition rulemaking. Based on stakeholder input and in consultation with FDA, we believe that the following EHR technology capabilities could help achieve our stated objectives:

- Record a minimum set of data elements for each UDI in a patient's implantable device list, including:
  - Labeler Name (Manufacturer);
  - Brand Name;
  - Version or Model;
  - Global Medical Device Nomenclature Name;
  - Single Use indicator;
  - Labeled as containing natural rubber latex or dry natural rubber; and
  - MRI Safety Status.
- Accept electronic UDI data via automatic identification and data capture (AIDC) or other assistive technologies used in health care systems (e.g., bar code scanners and radio frequency identification).
- Use the device identifier portion of the UDI to obtain and incorporate GUDID device identification attributes in the patient's implantable device list.
- Use the device identifier or production identifier portions of the UDI to generate lists of patients with a particular implantable device.
- Make a UDI and its associated identification attributes accessible to the EHR technology for reporting purposes (e.g., adverse event reporting, registry population, recalls).
- Exchange a UDI and UDI data with procedure reporting systems (including adverse event incident reporting systems and medical specialty reporting systems) and other systems that associate a patient with a device.
- Expand these and other capabilities to additional types of devices used by patients.

We solicit comment on whether to propose these capabilities (or a subset thereof) for adoption in a subsequent rulemaking. We also request comment on other standards, capabilities, or certification criteria that we have not

[38] These and other potential benefits of UDIs and the UDI system established by FDA are described in detail in the Unique Device Identification System Notice of Proposed Rulemaking, 77 FR 40736.

[39] For example, the HL7 Technical Steering Committee has initiated a UDI Task Force to ensure that UDI is implemented in a consistent and interoperable manner across the suite of HL7 standards. See *http://hl7tsc.org/wiki/index.php?title=TSC_Minutes_and_Agendas*. FDA is collaborating with the Engelberg Center for Health Care Reform at the Brookings Institute to develop a roadmap for the successful adoption and implementation of UDI throughout the healthcare system. See *http://www.brookings.edu/about/centers/health/projects/development-and-use-of-medical-devices/udi*. AHRQ has incorporated UDI and associated data attributes in its Common Formats for adverse event reporting. See *http://www.pso.ahrq.gov/formats/brochurecmnfmt.htm* . *Also* see AHRQ Data Dictionary, Common Formats Hospital Version 1.2, at 87, available at *https://www.psoppc.org/c/document_library/get_file?p_l_id=375680&folderId=431263&name=DLFE-15061.pdf*. Through an S&I Framework Structured Data Capture Initiative, ONC, FDA, and other stakeholders are pursuing the inclusion of UDI data in FDA adverse event reporting. See *http://wiki.siframework.org/Structured+Data+Capture+Initiative*. The inclusion of UDI data in FDA adverse event reporting is being pursued through an ONC S&I Framework Structured Data Capture Initiative, see *http://wiki.siframework.org/Structured+Data+Capture+Initiative*.

[40] This version is Release 2 of the Draft Standard for Trial Use, which is discussed in further detail under the 2015 Edition ''transitions of care'' certification criterion.

identified but that would further our stated aims. Finally, we specifically seek input on the list of data elements that we have identified and whether we should propose these or other data elements in connection with this criterion.

- Transitions of Care

MU Objective
The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.
2015 Edition EHR Certification Criteria
§ 170.315(b)(1) (Transitions of care)
Gap Certification Status
Ineligible

We propose to adopt a single 2015 Edition certification criterion for ''transitions of care'' (ToC). This proposed criterion would include significant modifications when compared to the two related 2014 Edition criteria adopted in the 2014 Edition Final Rule. This proposed criterion also reflects corresponding structural and clarifying changes that we have made to the proposed 2015 Edition ''clinical information reconciliation and incorporation'' certification criterion (discussed right after this criterion) and to the ''view, download, transmit to third party (VDT)'' certification criterion.

Our overall rationale for these proposed modifications is three-fold: 1) to further improve interoperability for ToC; 2) to improve the market availability of certified electronic exchange services for transport (and, thus, increase EPs, EHs, and CAHs' abilities to choose such services to demonstrate MU) by decoupling the 2014 Edition's ToC requirement to demonstrate both ''content'' and ''transport'' capabilities together in order to meet the two ToC certification criteria; and 3) to make the work-flow sequence we had in mind when we drafted the 2014 Edition criterion (at 45 CFR 170.314(b)(1)) clearer.

Interoperability for ToC is one of ONC's top priorities. ONC follows the definition of ''interoperability'' provided by the Institute for Electrical and Electronics Engineering Computer Dictionary which defines interoperability to mean: ''*the ability of two or more systems or components to exchange information and to use the information that has been exchanged.*''[41] With the adoption of a single content standard (Consolidated CDA) and ''transport''/transmission standards as part of the 2014 Edition ToC certification criteria as well as the requirement that all EHR technology be certified to support transmissions in accordance with the Applicability Statement for Secure Health Transport (the primary Direct Project specification),[42] we made significant strides toward this definition.

With that in mind, the 2014 Edition certification criteria and corresponding MU Stage 2 measures have generated a significant amount of questions, requests for clarifications, and feedback related to how the ToC certification requirements could be improved in light of on-the-ground experience and challenges. We have reviewed and considered all of this feedback since the 2014 Edition Final Rule and now propose a suite of changes that we believe will address stakeholder concerns as well as enhance interoperability for this priority use case.

''Decoupling'' Content and Transport

In the 2014 Edition Final Rule, we adopted two ToC certification criteria. The first, § 170.314(b)(1), requires EHR technology to be able to ''receive, display, and incorporate'' transition of care/referral summaries. The second, § 170.314(b)(2), requires EHR technology to be able to ''create and transmit'' transition of care/referral summaries.

These two 2014 Edition certification criteria require that EHR technology be able to ''receive'' and ''transmit'' a Consolidated CDA (''transition of care/referral summary'') in accordance with the Applicability Statement for Secure Health Transport (the primary Direct Project specification). Beyond the required transport standard (the primary Direct Project specification), we also included the option for EHR technology to be tested and certified to two other transport capabilities (i.e., Direct +XDR/XDM and SOAP + XDR/XDM).

As we indicated at the beginning of the preamble, the ''scope'' of a certification criterion begins at the second paragraph level of the regulatory section and encompasses all paragraph levels below the second paragraph level. Therefore, all capabilities under § 170.314(b)(1) and (b)(2)—including the transmission capabilities—must be demonstrated to meet each criterion as a whole. This means that under the 2014 Edition there is no way for EHR technology to be certified solely to perform the transport capabilities specified in each criterion.

Since the 2014 Edition Final Rule's publication, ONC has received specific feedback that this constraint or the ''binding'' of transport and content capabilities within the scope of a single certification criterion could impede innovation and limit EPs, EHs, and CAHs' market choices for electronic health information exchange services. Stakeholders also indicated that we had incorrectly imposed the coupling of technical capabilities that can be adequately performed by two different systems. They stated that content capabilities and transport capabilities should be separately tested and certified as the standard that supports one may change over time while the other remains the same.

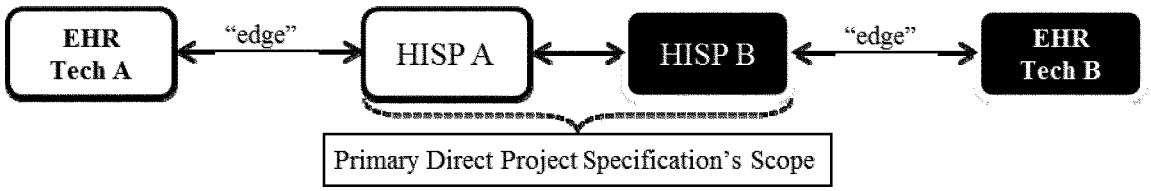
This issue is best illustrated by the requirement in both 2014 Edition ToC criteria that EHR technology demonstrate its conformance to the primary Direct Project specification. As shown in the figure below, the primary Direct Project specification is not an ''end-to-end'' specification. Rather, the primary Direct Project specification is applicable to capabilities that are typically performed by what are called Health Information Service Providers or

[41] See IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries (New York, NY: 1990).

[42] *http://wiki.directproject.org/file/view/Applicability+Statement+for+Secure+Health+Transport+v1.1.pdf.*

HISPs. At times, an EHR technology may be designed with fully integrated HISP functions, but it is equally likely that third-party intermediaries will perform these capabilities. As a result, our 2014 Edition ToC criteria have resulted in HISP functionality being built into EHR technology (or, conversely, EHR functionality being built into a HISP solely for the HISP to meet the certification criteria).

• Figure 1: The primary Direct Project specification's applicability.



We agree with stakeholder feedback that we should enable transport capabilities to be tested and certified separately from content capabilities. We also believe that permitting separate testing and certification for these capabilities would enable more transport-specific services to be certified as EHR Modules and, thus, would provide EPs, EHs, and CAHs with more choices in terms of the electronic health information exchange services they can use to demonstrate MU. Accordingly, we propose to adopt a single 2015 ToC certification criterion that focuses on content capabilities (create, receive, and display) and an EHR technology's ability to connect to a service that is conformant with the primary Direct Project specification through the use of a newly developed, ''ONC Implementation Guide for Direct Edge Protocols, Version 1.0, January 10, 2014'' (IG for Direct Edge Protocols),[43] which we propose to adopt at § 170.202(e). This proposal, in addition to our proposed revisions to the Base EHR definition to reference the 2015 Edition, continues to maintain and reinforce our overall policy that Certified EHR Technology must be able to perform transmissions in accordance with the primary Direct Project specification. The difference is that it enables transport capabilities to be separately tested and certified and separately implemented by EPs, EHs, and CAHs as a means to meet the Certified EHR Technology definition. We discuss our specific ''transmission'' certification criteria later in the preamble and our proposal to include them in a new regulatory paragraph ''(h)'' within § 170.315.

Edge Protocol for EHR to HISP Connectivity for ''Direct'' Transmissions

As illustrated by Figure 1 and the arrows labeled with ''edge,'' the primary Direct Project specification focuses on HISP-to-HISP transactions and not on EHR-to-HISP transactions. Since the 2014 Edition Final Rule, the stakeholder community that participates in the Direct Project has produced a new implementation guide to clarify for EHR technology developers the standardized protocols that should be used to connect to a HISP (i.e., EHR-to-HISP).

This new implementation guide specifies that both a ''Direct Edge System'' (i.e., EHR technology) and a ''Direct HISP System'' must support at least one of the following protocols: IMAP4, POP3, SMTP, or IHE XDR.

While we propose a separate certification criterion for conformance to the primary Direct Project specification, we seek to maintain the same policy outcome we set in the 2014 Edition (i.e., that every EHR technology certified to ToC is capable of performing transmissions in accordance with the primary Direct Project specification). As a result, we propose that the 2015 Edition ToC certification criterion specify that EHR technology demonstrate it can send and receive transition of care/referral summaries in a transmission—that conforms to the IG for Direct Edge Protocols—which is used by a service that has implemented the primary Direct Project specification.

In other words, testing and certification to this portion of proposed 2015 Edition ToC certification criterion would require that EHR technology be able connect to a HISP following the IG for Direct Edge Protocols and enable that HISP to subsequently transmit the transition of care/referral summary using the primary Direct Project specification to a recipient. We emphasize that while the standard adopted at § 170.202(a) is still referenced in this proposed criterion, its reference is to solely express the technical outcome we expect to be demonstrated by EHR technology—that a transmission from EHR-to-HISP is successful in that the HISP can subsequently transmit the transition of care/referral summary. Again, these proposed revisions are to make clear that as a result of our proposal, we would no longer require testing and certification to the primary Direct Project specification as a condition of meeting this certification criterion.

Updated Consolidated CDA Standard

As expressed in the 2014 Edition Final Rule, the Consolidated CDA standard is now the single standard permitted for certification and the representation of summary care records. It is referenced in four proposed 2015 Edition certification criteria (ToC, VDT, Clinical Summary, Data Portability). Industry stakeholders have continued to work to improve and refine the Consolidated CDA standard since the 2014 Edition Final Rule.[44] An updated version, HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.0,[45] was balloted in August and September 2013. A reconciliation of comments received during balloting will be completed prior to the issuance of a final rule for this proposed rule. The currently balloted version includes the following changes which we believe provide important clarifications and enhancements:

• Addition of new structural elements: new document sections and data entry templates:

○ New Document Templates for: Care Plan; Referral Note; Transfer Summary.

○ New Sections for: Goals; Health Concerns; Health Status Evaluation/Outcomes; Mental Status; Nutrition; Physical Findings of Skin.

○ New organizers and many new entries (e.g. Wound Observation).

• Some sections/entries were deprecated (i.e., not in use any longer).

[43] *http://wiki.directproject.org/file/detail/Implementation+Guide+for+Direct+Edge+Protocols+v1.0.pdf.*

[44] *http://wiki.siframework.org/Companion+Guide+to+Consolidated+CDA+for+MU2.*

[45] Access to the standard can be found at the following link, which requires the creation of an HL7 account: *http://www.hl7.org/documentcenter/public/ballots/2013SEP/downloads/CDAR2_IG_CCDA_CLINNOTES_DSTUR2_D1_2013SEP.zip.*

- Updates to (versioning of) template/section/entry object identifiers (OIDs).
  - This includes new chapter describing HL7's approach to template versioning.
- Tighter data constraints/requirements.
  - For example, some data elements with a ''MAY'' requirement now have a ''SHOULD'' requirement. Likewise, some with a ''SHOULD'' requirement now have a ''MUST'' requirement.
- Updated Vocabulary/Value Set constraints.
  - For example: two SNOMED CT codes were added to Current Smoking Status value set and Tobacco Use value set to support the 2014 Edition vocabulary requirements for patient smoking status.
  - NLM's VSAC was named as reference for Value Sets used in CCDA.

Accordingly, we propose to adopt the updated Consolidated CDA standard in § 170.205(a)(4) and we propose to reference its use in the proposed 2015 Edition ToC certification criterion as well as the three other certification criteria previously mentioned. We also propose to require (for reasons already provided as part our proposal for the ''implantable device list'' certification criterion) that EHR technology must be capable of including the UDI(s) for a patient's implantable device(s) as data within a created Consolidated CDA formatted document.

Shifting ''Incorporation'' From ToC to Clinical Information Reconciliation

The 2014 Edition ToC certification criterion at § 170.314(b)(1)(A) and (B) requires EHR technology to demonstrate ''[u]pon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3)'' that it can properly match the transition of care/referral summary received to the correct patient; and electronically incorporate medications, problems, and medication allergy data. At the beginning of the 2014 Edition Final Rule we responded to comments on our proposed description for ''incorporate'' (77 FR 54168–54169) and stated that, ''[w]e had revised our description of incorporation to reflect the common interpretation commenters stated they assigned to the term. Thus, when the term incorporate is used within a certification criterion it is intended to mean *to electronically process structured information from another source such that it is combined (in structured form) with information maintained by EHR technology and is subsequently available for use within the EHR technology by a user.''*

We also responded to comments on this issue at 77 FR 54218 and offered a more nuanced response in the context of the 2014 Edition ToC certification criterion at § 170.314(b)(1) and the clinical information reconciliation certification criterion at § 170.314(b)(4):

> [A]s we clarified in the beginning of this final rule, we intended for the term ''incorporate'' to mean that EHR technology would be able to process the structured data contained in those three Consolidated CDA sections (medications, problems, medication allergies) such that it could be combined (in structured form) with data already maintained by EHR technology and would subsequently be available for use, such as to be used as part of the clinical information reconciliation capabilities (expressed in the certification criterion adopted at (§ 170.314(b)(4)).

Stakeholders have indicated confusion regarding this preamble explanation and questioned the workflow assumption we had in mind when placing the ''incorporation'' capability in the ToC certification criterion. They indicated that in a typical workflow, inbound data is first reconciled and then incorporated (which makes it subsequently available for use within the EHR technology). Thus, our explanation that incorporated information as part of the ToC certification criterion would ''subsequently be available for use, such as to be used as part of the clinical information reconciliation capabilities'' misstated the workflow.

To avoid future confusion, the proposed 2015 Edition ToC certification no longer references the 2014 Edition's ''incorporation'' capabilities at § 170.314(b)(1)(A) and (B) and instead, we propose to place those capabilities in the proposed 2015 Edition ''clinical information reconciliation and incorporation'' certification criterion. We believe this revision will clarify the interplay between these two certification criteria and will clear up any misconceptions about the anticipated workflow. The specific capabilities for ''section views'' expressed at § 170.314(b)(1)(C) would continue to remain as part of our proposed 2015 Edition ToC criterion because they focus on content capabilities.

ToC Interoperability and MU Stage 2 ''Cross-Vendor'' Exchange Proposals

As part of the EHR Incentive Programs Stage 2 proposed rule, CMS proposed a new measure for its ''Transitions of Care objective'' that would have limited the new measure's numerator to only permit electronic transmissions to count if they were made to recipients that were: ''(1) Not within the organization of the transmitting provider; and (2) did not have Certified EHR Technology from the same EHR vendor'' (77 FR 13724). This proposal sought to use the EHR Incentive Programs to reward this outcome and, by virtue of setting this outcome, give EPs, EHs, and CAHs as well as EHR technology developers an explicit reason to implement solutions that promote interoperable electronic health information exchange.

Public comment on these proposals raised numerous concerns, including (among other issues) geographic market share constraints and undue burden because both limitations would be hard to do determine in an automated way. In response, CMS ultimately decided not to retain either of the proposed numerator limitations (77 FR 54019). CMS did, however, adopt a third ToC measure for MU Stage 2 that requires EPs, EHs, and CAHs to ''conduct one or more successful electronic exchanges of a summary of care document, which is counted in measure 2 with a recipient who has EHR technology designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or conduct one or more successful tests with the CMS designated test EHR during the EHR reporting period.''

While the measurement burden associated with the ''cross vendor'' numerator limitation proved too difficult a concept to implement, we have continued to consider ways to reach this same outcome. First, we keep in mind that the proposed cross-vendor numerator limitation was imposed on the ''sender.'' The sender, upon transmission of a summary care record, would need to know if the recipient had a different EHR technology developer's product than they did in order to determine whether that transmission could be counted in the numerator. Second, we considered solutions. One theoretical solution we considered would be to automate the sender's measurement. This would require EHR technology (through certification) to send an acknowledgement with the EHR technology developer's name or other identifier upon receipt of a summary care record. This ''solution,'' however, would require modifications to existing technical standards and would be insufficient (and really a partial solution) because EPs, EHs, and CAHs, can (today) electronically transmit summary care records to non-MU providers for ToC and count such transmissions in their numerator. Thus, health care providers who have no incentive to adopt CEHRT would not necessarily have the capability to

respond with this kind of acknowledgement and there would still be situations where EPs, EHs, and CAHs would have to manually count transmissions.

As we took a step back to assess this proposal's viability, we realized its purpose would be to solve a measurement problem and not an interoperability problem. Thus, we reassessed the true ''problem'' we (ONC) were trying to solve—interoperability—and, more specifically, the ''use'' aspect of the interoperability definition we follow. Given that our 2014 Edition ToC certification criteria require EHR technology to be able to receive and transmit Consolidated CDAs in accordance with the primary Direct Project specification, EPs, EHs, and CAHs will have the ability to ''exchange'' with any other EHR technology. However, it remains unclear whether each individual EP, EH, or CAH will be able to effectively use the Consolidated CDA it receives. While the Consolidated CDA is the only standard we permit for summary care record creation, its specifications permit a certain level of optionality and variability. As a result, while two different certified EHR technologies can accomplish ''exchange'' with a validly implemented Consolidated CDA, the recipient may be unable to correctly or accurately parse a part or all of the Consolidated CDA. Early feedback from a handful of stakeholders has indicated that such events do occur.

We believe that EHR technology certification can improve this aspect of interoperability and, in turn, get us closer to the ultimate outcome that was intended by the original MU Stage 2 proposal—which is that an EP, EH, or CAH could both exchange a Consolidated CDA with any other EHR technology and be able to subsequently use the Consolidated CDA it receives. This is a fundamental capability needed beyond MU and will be critical to help advance delivery reform goals. Achieving this interoperability goal also closes a gap that meaningful use policy is not well positioned to impact (i.e., the capabilities of a recipient of electronically transmitted health information).

To do this, we propose to adopt a ''performance standard'' that would require EHR technology to successfully electronically process validly formatted Consolidated CDAs no less than 95% of the time. Note that this creates different capability requirements for certification within this criterion for ''receive'' than it does for the capabilities associated with creation of a Consolidated CDA for transmission. In other words, for certification, EHR technology would be permitted to create a Consolidated CDA that conformed to a particular and acceptable variation of the Consolidated CDA standard (given the optionality in the standard). However, for receipt of Consolidated CDAs, EHR technology would need to be able to receive no less than 95% of all of the possible variations that could be implemented under the standard. We also clarify that this performance standard's scope would be limited to the Consolidated CDAs' implementation of the data we require in this certification criterion (i.e., testing for the performance standard would not go beyond the header requirements and specific data required by the certification criterion). This proposed outcome has the effect of requiring EHR technology to be resilient when it comes to receiving Consolidated CDAs that have been configured differently (i.e., able to handle differently formatted Consolidated CDA without failing). While it is not unreasonable (from a user's perspective) to expect their EHR technology to perform with 99% or greater accuracy when it comes to processing Consolidated CDAs, we believe that 95% would be an appropriate initial performance threshold to adopt while still ensuring that users are not adversely impacted by poor performance. As discussed in the S&CC January 2010 interim final rule (75 FR 2021), we defined the term *''standard''* in 45 CFR 170.102 and stated, ''[w]e believe the types of standards envisioned by Congress in the HITECH Act that would be most applicable to HIT are standards that are technical, functional, or performance-based.''

Accordingly, we propose to adopt this new performance standard in section 212 of part 170 entitled ''Performance Standards for Health Information Technology.'' Further, we propose to reference this performance standard in the proposed 2015 Edition ToC certification criterion as a capability that must be demonstrated to meet the certification criterion.

We seek comment on whether the performance level should be set to 95% and request that commenters provide accompanying rationale for why it should be lower or higher. Further, our early thoughts around the testing approach for this part of the certification criterion are that it would involve EHR technology receiving some number of Consolidated CDAs (e.g., 100 to 1000) each formatted slightly (but validly) differently, or produced by different EHR technologies previously through testing, or both. Given that testing could be conducted in numerous different ways, we seek input on and suggestions on the best way(s) to test this proposal. We also seek input from industry stakeholders on the best ways to identify additional guidance for the Consolidated CDA that will further reduce its implementation variability and, ultimately, make achieving this performance standard simply a byproduct of implementing a tightly specified implementation guide.

While there is still a risk that EHR technology developers could deploy electronic transmission capabilities in ways that continue to make it difficult for EPs, EHs, and CAHs to exchange Consolidated CDAs with EHR technologies designed by different EHR technology developers, we believe that this proposal in combination with potential future proposals in MU to increase electronic exchange requirements can achieve the overall outcome EPs, EHs, and CAHs expect—that they will be able to exchange summary care records and upon receipt be able to use them without additional burden.

''Create'' and Patient Matching Data Quality

In 2011, both the HITPC and HITSC made recommendations to ONC on patient matching. The HITPC made recommendations in the following five categories: Standardized formats for demographic data fields, internally evaluating matching accuracy, accountability, developing, promoting and disseminating best practices, and supporting the role of the individual/patient.[46] The HITSC made four recommendations: Detailing patient attributes that could be used for matching (in order to understand the standards that are needed), data quality, formats for these data elements, and what data are returned from a match request.[47] The standards recommended by the HITSC are as follows:

- *Basic Attributes:* Given Name; Last Name; Date of Birth; Administrative Gender.[48]
- *Other Attributes:* Insurance Policy Number; Medical Record Number; Social Security Number (or last 4 digits); Street Address; Telephone Number; Zip Code.

[46] *http://www.healthit.gov/sites/default/files/hitpc-transmittal-letter-priv-sectigerteam-020211.pdf.*

[47] *http://www.healthit.gov/FACAS/sites/default/files/standards-certification/8_17_2011Transmittal_HITSC_Patient_Matching.pdf.*

[48] Despite its inclusion of the word ''gender,'' ''Administrative Gender'' is generally used in standards to represent a patient's ''sex'' as male, female, or undifferentiated. See: *http://ushik.ahrq.gov/ViewItemDetails?system=hitsp&itemKey=83680000.*

• *Potential Attributes:* Email Address; Voluntary Identifiers; Facial Images; Other Biometrics.

In July 2013, ONC launched an initiative to reinvigorate public discussion around patient matching, to perform a more detailed analysis of patient matching practices, and to identify the standards, services, and policies that would be needed to implement the HITPC and HITSC's recommendations. Although this initiative's first phase focused on a common set of patient attributes that could be leveraged from current data and standards referenced in our certification criteria, we recognize that additional, broader industry needs exist when it comes to methods related to patient matching and the attributes with which matching is performed. Some of these broader needs include the ability to link patient data across time for a longitudinal record, linking across different data sources in a health information exchange organization/network, and linking administrative data to clinical data for outcomes research. Additionally, new matching techniques that are beginning to leverage novel and large data sources suggest that now is the right time to review patient matching needs across the industry at large and how EHR technology can be one part of the solution.

Given these initial findings, we propose to include a limited set of standardized data as a part of the ''Create'' portion of the ToC criterion to improve the quality of the data included in outbound summary care records. We seek comment on additional data to include and other constraints that could be applied to this data to improve its quality. To be clear, this proposal does *not* require EHR technology to capture the data upon data entry, but rather at the point when the data is exchanged (an approach commonly used for matching in HL7 transactions, IHE specifications,[49] Consolidated CDA (C–CDA) specification, and the eHealth Exchange). The proposed standardized data include: First name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex. Additional feedback we have received suggests that use of data elements that do not change over time (e.g., place of birth, maiden name) could improve the patient matching results. In the bulleted list below, we identify more constrained specifications for some of the standardized data we propose. Based on our own research, we do not believe that the proposed constraints to these data conflict with the Consolidated CDA. That being said, some proposed constraints may further restrict the variability as permitted by existing specifications and others may create new restrictions that do not currently exist within the Consolidated CDA. We propose that:

• For ''last name/family name'' the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0[50] (which addresses whether suffix is included in the last name field) be followed.

• For ''suffix,'' that the suffix should follow the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, Ph.D., ESQ)[51] and that if no suffix exists, the field should be marked as null.

• For ''date of birth,'' that the year, month and date of birth should be required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in the latter local time is assumed. If date of birth is unknown, the field should be marked as null.

• For ''current address'' and ''historical address,'' be represented in United States Postal Service (USPS)[52] format. And, if a historical address is unavailable, that the value should be entered as null.

• For ''phone numbers,'' the ITU format specified in ITU–T E.123[53] and ITU–T E.164[54] be followed and that the capture of home, business, and cell phone numbers be allowed.[55] Further, that if multiple phone numbers are present in the patient's record, all should be included in the Consolidated CDA and transmitted.

• For ''sex'' we propose to require developers to follow the HL7 Version 3 Value Set for Administrative Gender, which includes M (Male), (Female) and UN (Undifferentiated) as options.[56]

We seek comment on the proposed standardized data to improve patient matching, including whether other data or constraints on proposed data should be modified to better support patient matching practices and work flow. For example, stakeholders have suggested that using the United States Postal Service (USPS) ''Address Information'' application program interface (API) that standardizes addresses as a way to ensure addresses are formatted in a consistent manner. While we believe this idea has merit, the USPS terms and conditions[57] currently appear to exclude this API's use for this purpose because it only permits users to ''use the USPS Web site, APIs and USPS data to facilitate USPS shipping transactions only.'' Similarly, we request comment on how to best handle or anticipate changes to the way in which data may be represented in other rapidly evolving standards approaches. For instance, we are aware that V2 and V3 HL7 standards use an identical format for date of birth, but the more recent Fast Health Interoperable Resources (FHIR) standards framework uses a different format. Others have suggested that we need to adopt international standards for address, for military purposes or for patients who live outside of the U.S., but have health care delivered within the U.S. More specifically, USPS expects *numbers* for ZIP code. Thus, we would be interested in stakeholder feedback regarding what standards could best support international addresses (for example, ISO 19160–4[58] which appears on a trajectory to reference/include to Universal Postal Union (UPU) S42).[59]

In addition, we seek comment on approaches to address other recommendations from the HITSC. For example, data quality is an important aspect of patient matching success. We seek comment on methods that leverage the certification program, ways to test and measure data quality, and approaches to sharing best practices for improving data quality.

Finally, we seek comment on additional findings from the 2013 Patient Matching Initiative that include studying non-traditional attributes to understand the potential for matching improvement, developing open source algorithms for testing purposes or use by EHR technology developers, the development of a formalized structure for establishing best practices, advancing consumer engagement with and access to their demographic data

[49] *http://www.ihe.net/Technical_Frameworks/.*

[50] *http://www.caqh.org/pdf/CLEAN5010/258-v5010.pdf.*

[51] *http://www.caqh.org/pdf/CLEAN5010/258-v5010.pdf.*

[52] *http://pe.usps.com/text/pub28/.*

[53] *http://www.itu.int/rec/T-REC-E.123-200102-I/e.*

[54] *http://www.itu.int/rec/T-REC-E.164-201011-I/en.*

[55] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186.*

[56] *http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.1.11.1.*

[57] *https://secure.shippingapis.com/registration/.*

[58] *http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=64242.*

[59] *http://www.upu.int/uploads/tx_sbdownloader/sheetAddressingS42InternationalAddressingStandardsFactSheetEn.pdf.*

and attributes for correction or approval, and developing and/or disseminating options and training materials that improve data quality.

• Clinical Information Reconciliation and Incorporation

MU Objective
The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.
2015 Edition EHR Certification Criterion
§ 170.315(b)(2) (Clinical information reconciliation and incorporation)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion that revises the 2014 Edition version. As discussed in more detail directly above in the 2015 Edition ToC certification criterion section *Shifting ''Incorporation'' From ToC to Clinical Information Reconciliation* ''reconciliation'' and ''incorporation'' capabilities were referenced in two separate 2014 Edition certification criteria. For the reasons discussed in the 2015 Edition ToC section above, we propose that the 2015 Edition ''clinical information reconciliation and incorporation'' certification criterion include the capabilities that are part of the 2014 Edition ToC certification criterion at § 170.314(b)(1)(A) and (B). Again, we believe that this change will make the workflow designed to meet this certification criterion clearer.

We also solicit comment on whether for our 2017 Edition rulemaking we should broaden the data that this certification criterion requires to be reconciled beyond medications, medication allergies, and problems and, if so, what other data we should consider referencing. Additionally, we solicit comment on whether EHR technology should be required to retain the outside/external data source's provenance as part of the incorporation process.

• Electronic Prescribing

MU Objective
Generate and transmit permissible prescriptions electronically (eRx).
2015 Edition EHR Certification Criterion
§ 170.315(b)(3) (Electronic prescribing)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Incorporate Laboratory Tests and Values/Results

MU Objective
Incorporate clinical laboratory test results into Certified EHR Technology as structured data.
2015 Edition EHR Certification Criterion
§ 170.315(b)(4) (Incorporate laboratory tests and values/results)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition that includes the HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Laboratory Results Interface, Release 1 (US Realm) (S&I Framework LRI) with Errata [60] in the 2015 Edition ''transmission of electronic laboratory tests and values/results to ambulatory providers'' certification criterion. This IG is the same guide adopted for the equivalent 2014 Edition certification criteria, but with the errata. The errata address technical corrections and clarifications for interoperability with the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, DSTU Release 1, US Realm, 2013 [61] and other laboratory domain IGs.

As compared to the 2014 Edition certification criterion, we also propose more specific requirements for how EHR technology must be capable of electronically displaying the information included in a test report. This specificity would improve the consistency with how laboratory tests and values/results are displayed, which would also assist with laboratory compliance with CLIA as we discuss in more detail earlier in this section (III.A) of the preamble under the ''*Computerized Provider Order Entry—Laboratory.''* This functionality would require EHR technology to be capable of displaying the following information included in laboratory test reports it receives: (1) The information for a test report as specified in 42 CFR 493.1291(a)(1) through (a)(3) and (c)(1) through (c)(7); the information related to reference values as specified in 42 CFR 493.1291(d); the information for alerts and delays as specified in 42 CFR 493.1291(g) and (h); and the information for corrected reports as specified in 42 CFR 493.1291(k)(2).

We propose to adopt the updated S&I Framework LRI at § 170.205(j)(2), which requires the modification of the regulatory text hierarchy in § 170.205(j) to designate the standard referenced by the 2014 Edition version of this certification criterion at § 170.205(j) to be at § 170.205(j)(1). This regulatory structuring of the IGs would make the CFR easier for readers to follow.

• Transmission of Electronic Laboratory Tests and Values/Results to Ambulatory Providers

MU Objective
Provide structured electronic laboratory results to eligible professionals.
2015 Edition EHR Certification Criterion
§ 170.315(b)(5) (Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion that includes the HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Laboratory Results Interface, Release 1 (US Realm) (S&I Framework LRI) with Errata [62] in the 2015 Edition ''transmission of electronic laboratory tests and values/results to ambulatory providers'' certification criterion. This IG is the same guide adopted for the equivalent 2014 Edition certification criteria, but with the errata. The errata address technical corrections and clarifications for interoperability with the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, DSTU Release 1, US Realm, 2013 [63] and other laboratory domain IGs.

As compared to the 2014 Edition certification criterion, we also propose to include new functionality that would improve the consistency with how laboratory tests and values/results are sent, received, and displayed. This would also assist with laboratory compliance with CLIA as we discuss in more detail earlier in this section (III.A) of the preamble under the ''*Computerized Provider Order Entry—Laboratory.''* This new functionality would require EHR technology to be capable of including in the laboratory test reports it creates for electronic transmission: (1) The information for a test report as specified in 42 CFR 493.1291(a)(1) through (a)(3) and (c)(1) through (c)(7); the information related to reference values as specified in 42 CFR 493.1291(d); the information for alerts and delays as specified in 42 CFR 493.1291(g) and (h); and the information for corrected reports as specified in 42 CFR 493.1291(k)(2).

[60] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279.*

[61] We have proposed to adopt this implementation guide for the 2015 Edition ''CPOE for laboratory orders'' certification criterion.

[62] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279*

[63] We have proposed to adopt this implementation guide for the 2015 Edition ''CPOE for laboratory orders'' certification criterion.

We propose to adopt the updated S&I Framework LRI at § 170.205(j)(2), which requires the modification of the regulatory text hierarchy in § 170.205(j) to designate the standard referenced by the 2014 Edition version of this certification criterion at § 170.205(j) to be at § 170.205(j)(1). This regulatory structuring of the IGs would make the CFR easier for readers to follow.

• Data Portability

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(b)(6) (Data portability)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition ''data portability'' certification criterion that revises the 2014 Edition version. Our first proposal, for consistency across other certification criteria revisions, is to also have this certification criterion reference the updated Consolidated CDA (Draft Standard for Trial Use, Release 2.0) standard we discuss in more detail in the ToC certification criterion portion of this preamble. Our second proposal (for reasons already provided as part our proposal for the ''implantable device list'' certification criterion) is that EHR technology must be capable of including the UDI(s) for a patient's implantable device(s) as data within a created Consolidated CDA formatted document.

We also solicit public comment on the following:

(1) Whether we should rename this certification criterion ''data migration.'' Given that the ''view, download, transmit to 3rd party'' certification criterion addresses data availability from a patient's perspective, this certification criterion has always been more focused on data availability from a health care provider's perspective. We believe that a more precise label for this certification criterion could prevent confusion as to its focus.

(2) Whether we should consider adding more requirements for the 2017 Edition version of this certification criterion that we would propose in a future rulemaking and what those requirements should be. For example, should this criterion focus on an expanded time boundary to allow for more longitudinal data to be exported and should it reference more data? Can additional electronic notes be included in a data portability requirement with the addition of header metadata to support export/import functions?

(3) Whether we should change this certification criterion as part of a 2017 Edition proposal to promote a broader range of use cases, including: (1) Local access/query (i.e., a provider's ability to access their own data through, for example, an API); (2) targeted access/inter-organizational query (i.e., a provider's ability to query data from another provider or specific location, such as when one provider performs a ''targeted query'' to obtain a patient's information from another provider); and (3) distributed, multi-source access/query (i.e., a provider's ability to disseminate queries to multiple organizations). This change could result in multiple use case specific certification criteria if appropriate.

• Clinical Quality Measures

Electronically Processing eMeasures

None of our prior rulemakings have included a proposal to adopt standards and EHR technology capabilities focused on an EHR technology's ability to electronically process clinical quality measures (CQMs). Until now, we did not believe that there were mature enough standards with which the industry had experience. For our 2017 Edition rulemaking, we hope to propose for adoption a certification criterion focused on EHR technology's ability to electronically process CQMs. More specifically, we solicit comment on industry readiness to adopt the HL7 Health Quality Measures Format (HQMF) [64] standard for representing a clinical quality measure as an electronic document.

Quality measures encoded in the HQMF format are referred to as ''eMeasures.'' The standard was first brought to HL7 in 2009 through an initiative led by the National Quality Forum under CMS contract.[65] HQMF Release 1 (HQMF R1 or R1) defines data elements, structure, metadata, logic, and definitions of quality measures so that measure developers can encode their measures in this format for EHR queries.

HQMF Release 2 (HQRF R2 or R2) [66] was published in December 2013 and improves upon the HQMF R1. R2 improves readability using business names, includes logic sub-trees to avoid inline repetition, improves and expands expressivity, replaces poorly understood specific occurrences with set operators, and provides expression language support. Both R1 and R2 provide human-readable components and machine processable components. However, R2 is easier for EHR technology to electronically process compared to the prior version. HQMF R1 is supported in the Cypress [67] testing tool, CMS Measure Authoring Tool (MAT),[68] and through XSL Transforms to generate a human readable form of eMeasures. The MAT is a publicly available, web-based tool for measure developers to create eMeasures, and uses the Quality Data Model (QDM) [69] to define concepts used in quality measures so EHR and other clinical electronic systems can consistently interpret and locate the data required. ONC and CMS intend to upgrade the Cypress testing tool and MAT to support new versions of the standards.

In addition to HQMF R2, the HL7 Version 3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF), Release 1 (US Realm) was published in December 2013 to provide more specific guidance to implementers that are using HQMF R2. The QDM-based IG describes constraints on the HQMF R2 header and body elements and provides a standard structure to construct a quality measure. This promotes more accurate and consistent representation of quality measures for better care.

ONC and CMS are currently working with stakeholders to develop a unified set of standards that support both clinical quality measurement and clinical decision support. This includes a unified data model, a unified expression language, and unified meta-data standard. ONC and CMS are also working to modularize components of the existing standards (e.g., separate expression model, separate data model) so that any changes made in the future will affect only the relevant component of the standard, and will not require changes to the entire standard. Furthermore, modularization will allow the industry to swap out or replace components as needed as standards continue to evolve. These unified, modularized standards will likely require updates to already balloted versions of the quality measurement and CDS standards (e.g., HQMF, QRDA, HeD). Pending the availability of these unified standards for the 2017 Edition rulemaking, we anticipate proposing their adoption to more fully standardize CDS and CQM capabilities in EHR technology.

We solicit comment on industry support for unified, modularized CDS and CQM standards for the 2017 Edition. We also solicit comment on

[64] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97.*

[65] HL7 Version 3 Standard: Representation of the Health Quality Measures Format (eMeasures), Release 1 (HQMF R1).

[66] HL7 Version 3 Standard: Representation of the Health Quality Measures Format (eMeasure), Release 2 (December 2013) (HQMF R2).

[67] *http://projectcypress.org/.*

[68] *https://www.emeasuretool.cms.gov/.*

[69] *http://www.qualityforum.org/QualityDataModel.aspx.*

what we should require EHR technology to be able to demonstrate for certification (e.g., to require that EHR technology be able to electronically process any eCQM formatted in a unified, modularized CQM standard such as a new HQMF standard). To inform our future rulemaking, we also solicit comment on:

- Recommended testing and certification processes for the electronic processing of eCQMs;
- A way in which to classify measures so as to select a subset of measures that would be easier and simpler to be electronically processed by EHR technology in testing and certification;
- The ability/readiness of EHR technology to store and incorporate an eCQM in HQMF R2;
- The ability/readiness of EHR technology to map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information).

With the industry progress made to date with HQMF, we believe that this proposed rule provides an opportunity to introduce the HQMF standard for public comment. HQMF's broad adoption can help drive industry uptake of electronically processing eMeasures versus manually coding based on the human readable view of the eMeasures.

Functions and Standards for CQM Certification

To inform our 2017 Edition rulemaking, we solicit comment on what requirements for supplemental data and reporting should be included as part of CQM certification criteria. Quality reporting programs such as those required by states and CMS programs other than the EHR Incentive Programs may require additional supplemental data and capabilities beyond what ONC currently requires for certification. For example, the HIMSS EHR Association (EHRA) issued a letter to CMS in November 2013, citing variances between ONC's certification requirements and a supplemental implementation guide CMS issued ''Hospital Quality Reporting (HQR) Quality Reporting Document Architecture Category I Release 2 Supplementary Implementation Guide.'' [70] According to EHRA, these variances include, but are not limited to:

- ''The need to create QRDA–I reports on a per encounter basis rather than per patient, as had been required for certification;
- The EHR certification number must be assigned to each QRDA submission, an entirely new data element that would need to be added to databases and user interfaces in many cases;
- The new requirement to include the NPI/TIN for ''associated providers'' when the official Data Element Catalog referenced as a standard by ONC indicated that the NPI would only be required for EPs—again, a new data element with multiple implications for software development and provider usage.''

We also understand that quality reporting programs may require changes to existing standards (e.g., data element changes) that require industry (e.g., HL7) balloting and approval. These standards development timelines may not align with rulemaking cycles and, therefore, create discrepancies between what is required for certification versus what other programs may adopt. To better understand and address this issue in the future, we solicit comment on what specific capabilities, reporting requirements, standards, and data elements ONC should consider for CQM certification going forward.

Clinical Quality Measures—Capture and Export

MU Objective
N/A
2015 Edition EHR Certification Criteria
§ 170.315(c)(1) (Clinical quality measures—capture and export)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. However, we solicit public comment on the following in consideration of our upcoming 2017 Edition rulemaking. In the 2014 Edition Final Rule, we required that for certification to 170.314(c)(1) EHR technology be able to export a CQM data file formatted in accordance with the QRDA Category I standard. We solicit public comment on the potential usefulness of broadening the export requirement to also include reference to a QRDA Category II formatted data file, which would address the bulk reporting of quality data that includes the patient level data as outlined in the QRDA Category I report. A QRDA Category II report is a multi-patient-level quality report. Each report contains quality data for a set of patients for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on. Whereas a QRDA Category I report contains only raw applicable patient data, a QRDA Category II report includes flags for each patient indicating whether the patient qualifies for a measure's numerator, denominator, exclusion, or other aggregate data element. These qualifications can be pooled and counted to create the QRDA Category III [71] report [72] or the QRDA Category II report can be used for bulk or batch reporting of quality data.

- Clinical Quality Measures—Import and Calculate

MU Objective
N/A
2015 Edition EHR Certification Criteria
§ 170.315(c)(2) (Clinical quality measures—import and calculate)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

- Clinical Quality Measures—Electronic Submission

MU Objective
N/A
2015 Edition EHR Certification Criteria
§ 170.315(c)(3) (Clinical quality measures—electronic submission)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

- Clinical Quality Measures—Patient Population Filtering

MU Objective
N/A
2015 Edition EHR Certification Criteria
§ 170.315(c)(4) (Clinical quality measures—patient population filtering)
Gap Certification Status
Ineligible

We propose to adopt a new 2015 Edition certification criterion to require filtering of CQMs by patient population characteristics. Some newer CMS reporting programs may require the capability to support additional reporting filters. For example, the CMS Comprehensive Primary Care (CPC) initiative provides financial incentives to primary care providers in primary care practices who coordinate better care for their patients. In the CPC initiative, CMS determines the bonus payment based on the performance of an

[70] *http://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890124454&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DHQR_QRDAr2_DSTU_ImpGdV2_111513.pdf&blobcol=urldata&blobtable=MungoBlobs.*

[71] ONC has previously adopted the QRDA Categories I and III standards.

[72] QRDA Category III is used to report aggregate quality results (e.g., total number of patients in the numerator, total number of patients in the denominator).

''eligible practice site,'' not the individual provider. Similarly, the CMS Pioneer Accountable Care Organization (ACO) Model and Physician Quality Reporting System (PQRS) group practice reporting option (GPRO) provide payment based on ACO and group practice performance, respectively. Therefore, we propose to require that EHR technology be able to record structured data for the purposes of being able to filter CQM results to create different patient population groupings by one or a combination of the following patient characteristics:

- Practice site and address;
- Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/NPI combination;
- Diagnosis (e.g., by SNOMED CT code);
- Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles;
- Demographics including age, sex, preferred language, education level, and socioeconomic status.

To inform our proposal, we solicit comment on whether current CQM standards (e.g., QRDA Category I and Category III) can collect metadata for the characteristics listed above to filter and create a CQM report for a particular characteristic or combination of characteristics. We also solicit comment on vocabulary standards that could be used to record the characteristics proposed above.

- Authentication, Access Control, and Authorization

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities
2015 Edition EHR Certification Criterion
§ 170.315(d)(1) (Authentication, access control, and authorization)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. However, we solicit public comment on the issue of two-factor authentication to support two use cases: e-prescribing of controlled substances and remote provider access to EHR technology. In both the 2011 and 2014 Edition final rules, ONC's authentication-oriented certification criteria do not require that two-factor authentication be demonstrated as a capability in order to meet our certification criteria.

E-Prescribing Controlled Substances

In March 2010, the Drug Enforcement Agency (DEA) published an interim final rule entitled ''Electronic Prescriptions for Controlled Substances'' [73] (75 FR 16236). The rule removed the Federal prohibition against the electronic prescribing of controlled substances and requires a two-factor authentication protocol. Specifically, DEA permits authentication protocols that meet NIST LOA 3.[74]

More recently, the MU Stage 2 final rule (77 FR 53989–90) provided EPs participating in Stage 2 with an alternative denominator for the e-prescribing measure. This alternative allows EPs who are able to electronically prescribe controlled substances and want to count these prescriptions in the measure to do so.

Remote Provider Access to EHR Technology

In September 2012, the HITPC made recommendations regarding authentication standards that should be in place by the onset of MU Stage 3.[75] The HITPC recommended that ONC should move toward requiring multi-factor authentication (meeting LOA 3) by provider users who remotely access protected health information. In its recommendations, the HITPC described remote access to include the following scenarios: ''access from outside of an organization's/entity's private network, access from an IP address not recognized as part of the organization/entity or that is outside of the organization/entity's compliance environment, and access across a network any part of which is or could be unsecure (such as across the open Internet or using an unsecure wireless connection).''

Given the DEA's rule and the HITPC recommendations, we seek comment on whether we should consider two-factor authentication requirements for our 2017 Edition rulemaking. Specifically, we seek comment on:

(1) Whether we should adopt a general two-factor authentication capability requirement for certification. This requirement could complement e-prescribing of controlled substances requirements and more definitively support security requirements for remote access to EHR technology as well as any other EHR technology uses that may require two factor authentication. Note, given that DEA has its own 3rd-party assessors and available certification process for technology to demonstrate compliance with its rules, we have no intention nor do we believe that it would be prudent to duplicate DEA regulatory requirements in ours. In fact, two ONC–ACBs are also approved by DEA to perform its approved certification process.[76]

(2) Whether the HITPC's recommendations are appropriate and actionable and, if not, what level of assurance should be the minimum required for provider-users seeking remote access to EHR technology.

- Auditable Events and Tamper-Resistance

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities
2015 Edition EHR Certification Criterion
§ 170.315(d)(2) (Auditable events and tamper-resistance)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition ''auditable events and tamper-resistance'' certification criterion that revises the 2014 Edition version. The 2014 Edition ''auditable events and tamper-resistance'' certification criterion requires (at 45 CFR 170.314(d)(2)(ii)) that EHR technology must be set by default to perform the capabilities specified in (d)(2)(i)(A) of the criterion, and where applicable, (d)(2)(i)(B) and/or (C). The certification criterion, however, does not prohibit an EHR technology's audit log from being disabled by a user. Rather, the certification criterion requires access controls to be in place to restrict the ability to disable the audit log to a limited set of identified users and to record the user ID date/time when such a command is executed (45 CFR 170.314(d)(2)(i)(B)) to show who last ''touched'' the audit log before it was disabled.

In a 2013 report entitled ''Not All Recommended Safeguards Have Been Implemented in Hospital EHR Technology (OEI–01–11–00570),'' [77] the HHS Office of the Inspector General (OIG) recommended that we should propose a revision to this certification

[73] *http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm.*

[74] The National Institute of Standards and Technology (NIST) Special Publication 800–63–2 includes recommendations and guidelines for electronic authentication as well as defines four levels of authentication. Level 1 is the lowest assurance and Level 4 is the highest. Assurance Level 3 (LOA Level 3) provides multifactor remote network authentication. *http://csrc.nist.gov/publications/drafts/800-63-2/sp800_63_2_draft.pdf.*

[75] *http://www.healthit.gov/FACAS/sites/faca/files/transmittal_092512_pstt_recommendations_provider_authentication.pdf.*

[76] *http://www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm.*

[77] *https://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf.*

criterion to ''require that EHR technology keeps the audit log operational whenever the EHR technology is available for updates or viewing.'' Further the OIG stated that we should ''ensure that providers cannot or do not disable audit logs whenever the EHR technology is available for updates or viewing.'' As one basis for this recommendation, OIG found that ''ninety-six percent of hospitals reported that their audit logs remain operational at all times'' despite reporting barriers related to resources, user guides, and training.

In our response to OIG's report, we indicated our concurrence with its recommendation. Accordingly, we propose to adopt a 2015 Edition ''auditable events and tamper-resistance'' certification criterion that is similar to its 2014 Edition version, but that requires EHR technology to prevent all users from being able to disable the audit log through the EHR technology. The phrase ''through the EHR technology'' is meant to limit the scope of this capability to what is in the EHR technology's control and to be consistent with the same scope limitation expressed in the 2014 Edition version of this criterion that we placed on ''audit log protection'' at 170.314(d)(2)(iv) (77 FR 54235).

In the past, we had heard from stakeholders that there were reasons (e.g., performance concerns) to allow for audit logs to be disabled. Given that the proposed 2015 Edition certification criterion would prohibit that type of action from being performed in order for the EHR technology to be certified, we seek public comment on the impact and potential unintended consequences of such a change and specific examples where disabling an EHR technology's audit log is warranted.

- Audit Report(s)

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities
2015 Edition EHR Certification Criterion
§ 170.315(d)(3) (Audit report(s))
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. However, we solicit public comment on whether the ASTM E2147 standard will continue to remain sufficient for EHR technology certification for the 2017 Edition.

The standards adopted at 45 CFR 170.210(e) and referenced by the 2014 Edition ''auditable events and tamper-resistance'' and ''audit report(s)'' certification criteria require that EHR technology must be able to record audit log information as specified in sections 7.2 through 7.4, 7.6 and 7.7 of the standard adopted at 45 CFR 170.210(h). The standard adopted at 45 CFR 170.210(h) is ASTM E2147. Section 7.6 of ASTM E2147 specifies that audit log content needs to include the ''type of action'' and references six ''actions:'' additions, deletions, change, queries, print, and copy. Section 7.7 requires that the audit log record when patient data is accessed. So while not explicitly referenced in section 7.6, the action of ''access'' or viewing of a patient's information is also required to be recorded for certification.

Since the 2014 Edition Final Rule was published, we have received stakeholder feedback and questions regarding the actions specified at section 7.6 and their relationship to testing and certification in specific situations. Generally, these situations all pertained to stakeholders seeking confirmation that they should not have to support the auditing of capabilities that the EHR technology was not designed to perform. Specifically, stakeholders asked if EHR technology could still be certified if it were designed without one of the actions specified by the standard. For instance if the EHR technology did not include a ''copy'' function, did the EHR technology developer still need to design the audit log capability to record the ''copy'' action.

It was not our intention to require EHR technology developers to add in audit log functionality solely for certification purposes. We have interpreted this certification criterion requirement to mean that if the EHR technology does not include a capability for which an ''action'' is listed that testing and certification can proceed for the audit log process without EHR technology showing that it can record actions related to a non-existent capability. Any exception such as this for 2014 Edition testing is to be documented in the test report issued for the EHR technology, which is made publicly accessible on the Certified HIT Products List (CHPL) with the EHR technology.

Stakeholder feedback on this 2014 Edition certification criterion has brought up three issues on which we solicit public comment:

(1) The ''query'' action in section 7.6 of the ASTM E2147 standard is not a defined term in the standard's definition section (See section 3). As a result, we seek comment on whether this ambiguity has caused additional burden or challenges for EHR technology developers and how EHR technology developers have interpreted the term when designing their EHR technology. We also solicit comment on industry knowledge related to any plans to revise ASTM E2147 to address this ambiguity.

(2) Whether we should establish a minimum/baseline set of actions that EHR technology must always be capable of being audited. For instance, we could see the potential for ''copy,'' ''print,'' and ''query'' capabilities to *not* be included in certain EHR technologies. Thus, we could set a baseline that within section 7.6's actions, EHR technology must always support ''additions, deletions, and changes.''

(3) Are there other actions that we should consider specifying in an updated standard for the 2017 Edition that the current standard does not sufficiently address, such as the act of ''transmission''? We do not favor this approach because implementing it in regulation would cause us to add to the existing standard. Thus, we seek feedback on whether the standard is sufficiently up-to-date and appropriately specifies all of the actions necessary for EHR audit logs to capture.

(4) Finally, we seek comment on whether there are any alternative standards to ASTM E2147 that we should consider in light of the aforementioned concerns and ambiguities.

- Amendments; Automatic Log-Off; Emergency Access; End-User Device Encryption; Integrity

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities
2015 Edition EHR Certification Criteria
§ 170.315(d)(4) (Amendments)
§ 170.315(d)(5) (Automatic Log-Off)
§ 170.315(d)(6) (Emergency access)
§ 170.315(d)(7) (End-User Device Encryption)
§ 170.315(d)(8) (Integrity)
Gap Certification Status
Eligible (all five referenced)

We propose to adopt 2015 Edition EHR certification criteria that are the same as the 2014 Edition versions for all five of these certification criteria.

- Accounting of Disclosures

MU Objective
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities
2015 Edition EHR Certification Criterion

§ 170.315(d)(9) (Accounting of Disclosures)

Gap Certification Status

Eligible

We propose to adopt 2015 Edition certification criterion that is the same text as the 2014 Edition version. However, given our proposal to discontinue the Complete EHR concept and the associated regulatory definition (discussed later in this preamble), we also propose to remove the ''optional'' designation from this certification criterion as part of the 2015 Edition because such a designation would no longer be necessary. Further, we propose to continue to exclude it from the Base EHR definition in order to maintain policy consistency with the 2014 Edition and for the reasons discussed in our prior rulemakings regarding why we made it ''optional'' and excluded it from the Complete EHR definition.

• View, Download, and Transmit to Third Party

MU Objective

EPs

Provide patients, and their authorized representatives, the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP

EHs and CAHs

Provide patients, and their authorized representative, the ability to view online, download, and transmit information about a hospital admission

2015 Edition EHR Certification Criterion

§ 170.315(e)(1) (View, download, and transmit to third party)

Gap Certification Status

Ineligible

We propose to adopt a 2015 Edition criterion that revises the 2014 Edition version. The 2014 Edition View, Download and Transmit to Third Party (VDT) certification criterion requires EHR technology to provide patients (and their authorized representatives) with a secure online means to view, download, and transmit their health information to a 3rd party of their choice. It also requires EHR technology to keep an activity history log of the date and time a view, download, or transmission occurred and by whom. For the 2015 Edition version of this criterion, we propose several changes.

Clarified Introductory Text

We propose to make clarifying changes to the introductory text at 170.315(e)(1) to make it clear that this EHR technology capability is patient facing and for patients to use. Accordingly, we propose to revise the introductory text to lead with ''Patients (and their authorized representatives) must be able to use EHR technology to. . . .'' We also propose to use this same phrase at the beginning of each specific capability for VDT to reinforce this point.

For the same reasons discussed in the proposed 2015 Edition ToC certification criterion, we propose to reference the updated version of the Consolidated CDA (Draft Standard for Trial Use, Release 2.0), which we propose for adoption in this certification criterion.

Removing Ambiguity from ''Download''

We propose to revise the language for ''download'' to leave no room for any alternative interpretation. Specifically, we propose revising that language to stress that a patient must be able to download an ambulatory or inpatient summary in only the human readable format if they just want that, in only the Consolidated CDA format if they just want that, or in both formats if they want both. Although the 2014 Edition Final Rule's preamble for the 2014 Edition of this criterion expressed that a patient needed to be able to download either as their choice (meaning that EHR technology needed to support both methods), the ''or'' in the regulation text and our avoidance of using ''and/or'' (which can be equally confusing) led stakeholders to misinterpret the requirement's meaning when not read with the preamble.

Decoupling Transport and Content

For the same above-noted reasons we provide in the proposed 2015 Edition ToC certification criterion, we propose to ''decouple'' the transport and content capabilities in the 2015 Edition version of VDT. Similar to the ToC revisions, this certification criterion will now focus on content requirements and EHR technology's ability to demonstrate conformance with the IG for Direct Edge Protocols and enable a successful transmission. Certification for transmit is now a separate stand-alone requirement that can support ToC as well as VDT. The proposed requirements at § 170.315(e)(1)(i)(C):

(1) clearly express the need to support a patient's ability to choose the destination to whom they want to send their health information; and

(2) would require that EHR technology enable a patient to accomplish a transmission (of their own health information) that conforms to the IG for Direct Edge Protocols and is used by a service that has implemented the primary Direct Project specification.

By ''accomplish,'' we clarify that our expectation and our anticipated approach through testing would be that the transmitted Consolidated CDA arrives at its destination. This change would permit EHR technology developers seeking testing and certification to this proposed criterion to demonstrate compliance with the transmission requirement without having to be a HISP. They would, however, need to show that they can connect to one by conforming to the IG for Direct Edge Protocols and that the HISP successfully transmitted the ambulatory summary or inpatient summary to the patient's specified destination using the Direct Project specification. Demonstrating this outcome could be expedited if the EHR technology developer uses a service that is certified to enable health information to be electronically transmitted in accordance with the primary Direct Project specification (under our new proposal for this to be a separate certification criterion).

We clarify that the phrase ''[e]nter a 3rd party destination of their choice'' in the certification criterion does not require EHR technology to support every possible method a patient could conceivably choose. Rather, EHR technology must be able to support at least the entry of *any* ''Direct address,'' which is the minimum required by this certification criterion. We also note that from our perspective it is unacceptable for this transmission capability to in any way limit a patient's ability to send their health information to any existing and working ''Direct address.''

We seek comment on whether we should require another transmission method as part of this certification criterion in addition to the one just discussed.

Updated Consolidated CDA Version

We propose, for consistency across other certification criteria revisions, to also have this certification criterion reference the updated Consolidated CDA standard (Draft Standard for Trial Use, Release 2.0) we discuss in more detail in the ToC certification criterion portion of this preamble. Similarly, we propose (for reasons already provided as part our proposal for the ''implantable device list'' certification criterion) that EHR technology must be capable of including the UDI(s) for a patient's implantable device(s) as data within a created Consolidated CDA formatted document.

View

As discussed in our proposal for the 2015 Edition ''implantable device list''

certification criterion, we propose to add ''implantable device information'' as data that EHR technology would need to be capable of making available to a patient under the ''view'' capability.

Activity History Log

We propose to include two new data points in the 2015 Edition VDT criterion related to the activity history log. We propose that the addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed) be recorded. Although the 2014 Edition VDT criterion requires that the action of ''transmit'' be recorded, we did not specify that the intended destination be recorded. We believe this transactional history is important for patients to be able to access, especially if they actively transmit their health information to a 3rd party or another health care provider.

WCAG 2.0 Level AA

Consistent with our belief that all patients should have an equal opportunity to access their electronic health information without barriers or diminished functionality or quality, we proposed in the 2014 Edition NPRM (77 FR 13840) that the viewing capability for VDT must meet Level AA conformance with the most recent set of the Web Content Accessibility Guidelines (WCAG). The most recent set of guidelines (WCAG 2.0) were published in 2008 [78] and are organized under 4 central principles with testable ''success criteria:'' Perceivable, Operable, Understandable, and Robust. Each guideline offers 3 levels of conformance: A, AA, and AAA. WCAG 2.0 Level A (Level A) conformance corresponds to the most basic requirements for displaying Web content. WCAG 2.0 Level AA (Level AA) conformance provides for a stronger level of accessibility by requiring conformance with Level A success criteria as well as Level AA specific success criteria. WCAG 2.0 Level AAA (Level AAA) conformance comprises the highest level of accessibility within the WCAG guidelines and includes all Level A and Level AA success criteria as well as success criteria unique to Level AAA.

In the 2014 Edition Final Rule (77 FR 54179) we considered public comment and ultimately adopted Level A for accessibility, but indicated our interest in raising this bar over time. As a result, we propose for the 2015 Edition VDT criterion that EHR technology be compliant with Level AA. We propose to adopt this standard at § 170.204(a)(2). Note, to implement this proposal, we would have to modify the regulatory text hierarchy in § 170.204 to designate the accessibility standard referenced by the 2014 Edition VDT certification criterion at § 170.204(a) to be at § 170.204(a)(1). Level AA provides a stronger level of accessibility and addresses areas of importance to the disabled community that are not included in Level A. For example, success criteria unique to Level AA include specifications of minimum contrast ratios for text and images of text, and a requirement that text can be resized without assistive technology up to 200 percent without loss of content or functionality. We recognize that Level AA is a step up from Level A and request public comment on whether there are particular key elements of Level AA that we could adopt as hybrid between Level A and AA in an effort to prioritize key focus areas for accessibility improvements.

We also understand that there are not separate guidelines for ''mobile accessibility'' and that mobile is considered by the W3C Web Accessibility Initiative to be covered by the WCAG 2.0 guidelines.[79] Further, we would note that in September 2013, the W3C published a working group note consisting of ''Guidance on Applying WCAG 2.0 to Non-Web Information and Communications Technologies (WCAG2ICT).'' [80] We request public comment (especially from EHR technology developers that have sought or considered certification to the 2014 Edition VDT certification criterion with a ''non-web'' application) on what, if any, challenges exist or have been encountered when applying the WCAG 2.0 standards.

2017 Edition Issues for the VDT Certification Criterion under Consideration Images and Non-Text Data

In the 2014 Edition NPRM we proposed to require EHR technology to be capable of enabling images formatted according to the Digital Imaging and Communications in Medicine (DICOM) standard to be downloaded and transmitted to a third party (77 FR 13840). We stated our belief that this specific capability has the potential to empower patients to play a greater role in their own care coordination and could help assist in reducing the amount of redundant and duplicative imaging-oriented tests performed. In response to public comment, however, we did not adopt this proposal. In considering improvements that could be made to the VDT certification criterion for the 2017 Edition, we request public comment on whether we should again propose to require that images be part of this criterion. More specifically, we seek comment on: (1) Whether images for patients need to be of diagnostic quality; (2) whether they should be viewable and downloadable, but not required to be transmitted; and (3) whether cloud-based technology could allow for a link to the image to be made accessible. We also seek comment on other non-text data that we could require EHR technology to be able to make available to patients such as ECG waveforms.

''OpenNotes''

We also solicit public comment on whether a 2017 Edition VDT certification criterion should enable ''OpenNotes'' [81] functionality for EPs, EHs, and CAHs, to give patients the ability to gain access to their visit notes. The OpenNotes initiative was led by Beth Israel Deaconess Medical Center through a grant from the Robert Wood Johnson Foundation whereby ''researchers undertook a year-long trial of OpenNotes in which 105 doctors shared their notes with more than 19,000 patients in Boston, rural Pennsylvania, and Seattle.'' [82] Additionally, in April 2013, the Department of Veterans Affairs announced that it had enabled OpenNotes through its My HealtheVet Blue Button.[83]

• Clinical Summary

MU Objective
Provide clinical summaries for patients for each office visit
2015 Edition EHR Certification Criterion
§ 170.315(e)(2) (Ambulatory setting only—clinical summary)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition ''clinical summary'' certification criterion that revises the 2014 Edition version. Specifically, we propose to reflect the clarifications we provided in FAQ 33,[84] *require* the use of CVX codes for immunizations, and reference the updated Consolidated CDA version (Draft Standard for Trial Use, Release 2.0) in this criterion for consistency across our 2015 Edition and for the

[78] *http://www.w3.org/TR/WCAG20/.*

[79] *http://www.w3.org/WAI/mobile/.*

[80] *http://www.w3.org/TR/wcag2ict/.*

[81] *http://www.myopennotes.org/what-is-opennotes-2/.*

[82] *http://www.rwjf.org/en/grants/grantees/OpenNotes.html.*

[83] *http://www.rwjf.org/en/blogs/pioneering-ideas/2013/04/why_the_va_embraces.html.*

[84] *http://www.healthit.gov/policy-researchers-implementers/33-question-12-12-033.*

other reasons stated already in the proposed 2015 Edition ToC certification criterion. We also propose (for reasons already provided as part our proposal for the ''implantable device list'' certification criterion) that EHR technology must be capable of including the UDI(s) for a patient's implantable device(s) as data within a created Consolidated CDA formatted document.

The regulation text of the 2015 Edition ''clinical summary'' certification criterion clarifies that for medications administered during the visit, diagnostic tests pending after the visit and future scheduled tests, EHR technology must demonstrate the capability to represent the data using the specified vocabulary standard, where appropriate. FAQ 33 encourages the use of CVX codes for immunizations since the code set was not actually specified in the 2014 Edition ''clinical summary'' certification criterion. To correct this oversight, the 2015 Edition ''clinical summary'' certification criterion specifically includes the required use of CVX codes for immunizations. For diagnostic tests pending and future scheduled tests, we propose to require the use of LOINC®. We request comment, however, on whether LOINC® can be used to represent all possible diagnostic tests pending and future scheduled tests.

We also reiterate the situational dependency (office visit dependent) of certain data that the EHR technology must be able to provide, and limit, in the clinical summary to meet the proposed 2015 Edition certification criterion as well as the 2014 Edition ''clinical summary'' certification criterion. Although the regulation text for medications, diagnostic tests pending, and future scheduled tests may seem redundant with the Common MU Data Set, this data along with immunizations is specified separately because EHR technology must have the capability to limit this data in a clinical summary it creates to only those medications and immunizations administered during the visit and/or the diagnostic tests pending and future scheduled tests after the visit. In terms of customization of the clinical summary, this permits the user to limit this data in the clinical summary if so desired by the user. While providing historical data for medications, immunizations, and diagnostic tests in the clinical summary may be of benefit in certain instances, EHR technology is not required to have these capabilities to meet the certification criterion. This certification criterion, like the 2014 Edition ''clinical summary'' certification criterion, is meant to support the associated MU objective and measure that seeks to provide a patient with a record of the visit and specific lab tests or specific follow-up actions and treatment related to the visit.

• Secure Messaging

MU Objective
Use secure electronic messaging to communicate with patients on relevant health information
2015 Edition EHR Certification Criterion
§ 170.315(e)(3) (Ambulatory setting only—secure messaging)
Gap Certification Status
Eligible
We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Immunization Information

MU Objective
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice
2015 Edition EHR Certification Criterion
§ 170.315(f)(1) (Immunization information)
Gap Certification Status
Eligible
We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

• Transmission to Immunization Registries

MU Objective
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice
2015 Edition EHR Certification Criterion
§ 170.315(f)(2) (Transmission to immunization registries)
Gap Certification Status
Ineligible
We propose to adopt a 2015 Edition certification criterion that revises the 2014 Edition version. The 2014 Edition EHR certification criterion for transmission to immunization registries at § 170.314(f)(2) references the following IG for immunization messaging: HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.4.

Since the publication of the 2014 Edition Final Rule, CDC has issued an updated IG (HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5) that promotes greater interoperability between immunization registries and EHR technologies. Release 1.5 focuses on known issues from the previous release and revises certain HL7 message elements to reduce differences between states and jurisdictions for recording specific data elements. Specifically, Release 1.5 [85]:

• Clarifies and tightens conformance statements;

• corrects ACK (acknowledgment) messages to support improved messaging back to the EHR about the success/failure of a message;

• includes query and response changes such as V2.7.1 MSH user constraints, minimum requirements for a response message, and corrected profiles for response to errors and no match situations.

We believe these improvements are important to the IG and will continue to support our ultimate goal for this certification criterion—bidirectional immunization data exchange. Given the improvements included in the updated IG, we propose to adopt it at § 170.205(e)(4) and include it in the 2015 Edition ''transmission to immunization registries'' certification criterion at § 170.315(f)(2).

We have received stakeholder comments that the immunization registry community is moving toward, but has not yet developed fully mature standards for bidirectional data exchange that include immunization forecasting/CDS. We seek public comment on the maturity of bidirectional immunization data exchange activities and whether we should propose to include bidirectional immunization data exchange as part of the 2015 Edition and/or 2017 Edition.

National Drug Codes for Vaccine Coding

Our 2014 Edition requires the use of the CVX codes [86] to record vaccines administered.[87] CDC developed and maintains the list of CVX codes. The National Drug Code (NDC) vocabulary serves as a universal product identifier for drugs, and FDA publishes the list of NDC numbers as part of the NDC Directory.[88] In our 2011 Edition final rule, commenters noted that they were not aware of a mapping from NDC to CVX codes (75 FR 44614), and we did not believe that NDC codes were appropriate for representing immunizations at the time. However, since then CDC has begun a process to map National Drug Codes (NDC) to CVX

[85] This IG will be available for review during the public comment period at *http://www.cdc.gov/EHRmeaningfuluse/guides.html.*

[86] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx.*

[87] § 170.314(b)(2), § 170.314 (b)(7), and § 170.314(e)(2).

[88] *http://www.fda.gov/drugs/informationondrugs/ucm142438.htm.*

codes.[89] Stakeholders have expressed support for moving to NDC codes for vaccines because NDC codes:

- Are used for pharmaceutical inventory management within immunization registries, and therefore built into the immunization workflow;
- Are built into 2D barcodes which have been successfully piloted for vaccines (see comment solicitation for 2D barcoding for more information);
- Can improve safety with better specificity of vaccine formulation.

In addition, FDA has worked with HL7 to improve assignment of NDC codes to vaccines to reduce the reuse of NDC codes, an issue which has presented itself in the past.

NDC codes are structured in three parts: labeler, product, and packaging subcodes. Thus, historical vaccinations cannot be recorded using NDC codes because the exact formulation (e.g., product portion) is usually unknown. For example, a patient may report that he or she received the influenza vaccine one year ago, but does not know which influenza vaccine he or she received. We are aware of two possible solutions to record historical vaccinations if we were to move to replace CVX with NDC codes:

- Option #1: Continue to use CVX codes for historical vaccinations only;
- Option #2: Use the NDC syntax and create a new value set for the product portion of the code for vaccines of unspecified formula (e.g., influenza vaccine of unspecified formula) for historical vaccinations (resulting in an ''NDC-like'' code).

Given these issues, we solicit comment for the 2017 Edition on whether we should move to using NDC codes for vaccines to replace CVX and the preferred option for recording historical immunizations. We also solicit comment on other vocabularies that could be used to replace CVX. For example, we currently require RxNorm for medications and medication allergies in the 2014 Edition. We are aware that RxNorm codes include NDC codes as attributes, and it is possible to go from an NDC to an RxNorm standard normalized name.[90] Last, in our 2011 Edition final rule, we noted that CPT codes were not a better alternative to CVX because CPT codes are used for billing purposes and there is a public mapping of CPT to CVX codes [91] (75 FR 44614).

- Transmission to Public Health Agencies—Syndromic Surveillance

MU Objective
  Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice
Revised 2014 Edition EHR Certification Criterion
  § 170.314(f)(3) (Transmission to public health agencies—syndromic surveillance)
2015 Edition EHR Certification Criterion
  § 170.315(f)(3) (Transmission to public health agencies—syndromic surveillance)
Gap Certification Status
  Ineligible if certified prior to the effective date of the 2015 Edition Final Rule
  Eligible if certified after the effective date of the 2015 Edition Final Rule

We propose to revise the 2014 Edition syndromic surveillance certification criterion and adopt an identical 2015 Edition version.

Electronic syndromic surveillance data is valuable for early detection of outbreaks, monitoring disease and condition trends, and providing reassurance that an outbreak has not occurred. Syndromic surveillance can also inform community efforts to track and control chronic conditions. For both MU Stages 1 and 2, EPs may choose the ''electronic syndromic surveillance data'' objective under the menu set. In the MU Stage 2 final rule, CMS stated that very few public health agencies were accepting syndromic surveillance data from ambulatory, non-hospital providers, and there was no corresponding IG available at the time of the final rule's publication (77 FR 54025). They also noted that the CDC was working with the syndromic surveillance community to develop a new IG for ambulatory reporting of syndromic surveillance data, which was expected to be published in spring 2013.

Only a few public health agencies are currently accepting syndromic surveillance data from the ambulatory setting using HL7 2.5.1. Due to lack of demand, the CDC no longer plans to develop an HL7 2.5.1 IG for ambulatory reporting of syndromic surveillance data. Without such an IG most public health agencies will not have enough specific guidance to build systems to receive syndromic surveillance data from the ambulatory setting formatted to HL7 2.5.1. The MU Stage 2 final rule states that an EP, EH, or CAH may claim an exclusion if the public health agency does not have the capacity to accept reporting (77 FR 54021). Thus, many EPs may qualify for an exclusion for this objective and associated measure and, as a result, would need to choose another objective from the menu set on which to report.

Given the lack of an ambulatory IG for HL7 2.5.1, we propose to revise the 2014 Edition certification criterion. The proposed revisions to the 2014 Edition certification criterion would allow EHR technology designed for the ambulatory setting to be certified to alternative standards that support other modes of electronic syndromic surveillance data submission. In this regard, we are aware that syndromic surveillance data is currently being sent to public health agencies through new query-based models, including the QueryHealth initiative.[92] Query-based models take patient level data, de-identify it, and aggregate it for population health use. We understand that these query-based models use HL7 CDA and QRDA III standards, and do not necessarily use the HL7 2.5.1 standard. CDA and QRDA III standards were adopted and referenced by 2014 Edition certification criteria and, as a result, have become more widely implemented.

In light of the potential that many EPs may qualify for an exclusion for the MU objective and associated measure with which this certification criterion correlates, we seek to make available additional electronic syndromic surveillance submission capabilities in order to better support their opportunity to receive credit for the syndromic surveillance MU objective. Therefore, we propose to revise the 2014 Edition syndromic surveillance certification criterion at § 170.314(f)(3) to include the HL7 CDA and QRDA III standards as alternative standards to HL7 2.5.1 for EHR technology certification designed for the ambulatory setting.

We propose to revise the 2014 Edition syndromic surveillance certification criterion by replacing the referenced IG for the HL7 2.5.1 standard (for the inpatient setting) with an updated version that incorporates an addendum clarifying conformance guidance. Specifically, we propose to move to the updated implementation specification PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, and Inpatient Settings, Release 1.9 (April 2013) [93] and adopt it at § 170.205(d)(4). We believe that HL7 2.5.1 is the only appropriate standard for inpatient setting certification as an IG exists and many hospitals and public

[89] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc.*

[90] See ''Where does RxNorm get its data?'' at *http://www.nlm.nih.gov/research/umls/rxnorm/overview.html.*

[91] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt.*

[92] *http://wiki.siframework.org/Query+Health.*

[93] *http://www.cdc.gov/phin/library/guides/PHIN%20MSG%20Guide%20for%20SS%20Final_508readyRelease1_9%2004%2027%202013.pdf.*

health agencies are using the standard to exchange syndromic surveillance data. The alternative HL7 CDA and QRDA III standards we propose to include in the revised 2014 Edition syndromic surveillance certification criterion for the ambulatory setting are standards we have already adopted as part of the 2014 Edition. With respect to the HL7 CDA standard, we also propose to adopt it at § 170.205(d)(5), which is under the specific syndromic surveillance hierarchy in our regulation text. The proposed adoption of this standard here is meant to clearly indicate the transmission to which this standard is to be applied.

We propose to adopt a 2015 Edition syndromic surveillance certification criterion at § 170.315(f)(3) that includes these same standards and is identical to the proposed revised 2014 Edition syndromic surveillance certification criterion.

We solicit comment on whether public health agencies are using the QRDA Category I standard to receive query-based syndromic surveillance data, and whether ONC should consider adopting the QRDA Category I standard for the ambulatory setting.

The gap certification status indicated in the table for this certification criterion is split because we have proposed to modify the 2014 Edition syndromic surveillance certification criterion. If EHR technology is certified prior to the effective date of a final rule for this 2015 Edition proposed rule, then it will be certified to the current ''unrevised'' version of the 2014 Edition syndromic surveillance certification criterion. EHR technology certified to the ''unrevised'' version of the 2014 Edition syndromic surveillance certification criterion would be ineligible for gap certification to the 2015 Edition syndromic surveillance certification criterion because of the proposed changes to the 2015 Edition syndromic surveillance certification criterion. However, if EHR technology is certified after the effective date of a final rule for this 2015 Edition proposed rule, the EHR technology could be certified to the proposed revised 2014 Edition syndromic surveillance certification criterion. This would then make the EHR technology eligible for gap certification to the 2015 Edition syndromic surveillance certification criterion because the proposed 2015 Edition syndromic surveillance certification criterion would be ''unchanged'' when compared to the proposed revised 2014 Edition syndromic surveillance certification criterion.

• Transmission of Reportable Laboratory Tests and Values/Results

MU Objective
Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice
2015 Edition EHR Certification Criterion
§ 170.315(f)(4) (Inpatient setting only—Transmission of reportable laboratory tests and values/results)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion that revises the 2014 Edition version. We also propose to make a technical amendment to the regulation text for the 2014 Edition criterion in order to have it continue to point to the appropriate standard and implementation specifications (HL7 2.5.1 and HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification) after we restructure the regulatory text hierarchy at § 170.205(g) to our accommodate our 2015 Edition proposal.

Since the publication of the 2014 Edition Final Rule, CDC has issued an updated implementation guide (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, DSTU, Release 2 (US Realm), 2013) that address technical corrections and clarifications for interoperability with laboratory orders and other laboratory domain implementation guides. Specifically, Release 2: [94]

• Corrects errata;
• Applies conformance statements and condition predicates from the Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification;
• Provides technical corrections;
• Provides additional guidance and clarifications;
• Aligns with the current S&I Framework v2 messaging guide in the laboratory space (Release 1 was aligned with the LRI predecessor issued by Healthcare Information Technology Standards Panel).

We believe these improvements are important to the IG and will continue to support interoperability. Given the improvements included in the updated IG, we propose to adopt it at § 170.205(g)(2) and include it in the 2015 Edition ''transmission of reportable laboratory tests and values/results'' certification criterion at § 170.315(f)(4). As noted above, to properly codify this proposal in regulation, we would have to modify the regulatory text hierarchy in § 170.205(g) to designate the standard and implementation specifications referenced by the 2014 Edition ''transmission of reportable laboratory tests and values/results'' certification criterion at § 170.205(g)(1) instead of its current designation at § 170.205(g).

• Cancer Case Information

MU Objective
Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice
2015 Edition EHR Certification Criteria
§ 170.315(f)(5) (Ambulatory setting only—cancer case information)
Gap Certification Status
Eligible

We propose to adopt a 2015 Edition EHR certification criterion for cancer case information that is the same as the 2014 Edition version. However, given our proposal to discontinue the Complete EHR concept and associated regulatory definition (discussed later in this preamble), we also propose to remove the ''optional'' designation from this certification criterion as part of the 2015 Edition since such designation would no longer be necessary.

• Transmission to Cancer Registries

MU Objective
Capability to identify and report cancer cases to a State cancer registry, except where prohibited, and in accordance with applicable law and practice
2015 Edition EHR Certification Criteria
§ 170.315(f)(6) (Ambulatory setting only—transmission to cancer registries)
Gap Certification Status
Ineligible

We propose to adopt a 2015 Edition certification criterion for transmission to cancer registries that revises the 2014 Edition version. Given our proposal to discontinue the Complete EHR concept and associated regulatory definition (discussed later in this preamble), we also propose to remove the ''optional'' designation from this certification criterion as part of the 2015 Edition since such designation would no longer be necessary.

We propose to make a technical amendment to the regulation text for the

[94] This IG will be available for review during the public comment period at *http://www.cdc.gov/EHRmeaningfuluse/guides.html.*

2014 Edition certification criterion so that it continues to point to the appropriate standard [95] in the regulatory text hierarchy at § 170.205(i), while accommodating our 2015 Edition proposal. Specifically, we propose to modify the 2014 Edition certification criterion to reference § 170.205(i)(1) to establish the regulatory text hierarchy necessary to accommodate the standard and IG referenced by the proposed 2015 Edition certification criterion.

The 2014 Edition criterion for transmission to cancer registries at § 170.314(f)(6) references the following IG for cancer reporting: Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0. Since the publication of the 2014 Edition Final Rule, CDC has updated the IG (Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.1, March 2014) to address technical corrections and clarifications for interoperability with EHRs and cancer registries. Specifically, this updated version of the IG: [96]

- Provides clarification about conformance statements taking precedence over table constraints;
- Adds new vocabulary link (ICD 10 CM reportability list);
- Fixes some within-document references;
- Fixes some LOINC Codes;
- Fixes some Code System and Value Set Object Identifiers (OIDs);
- Fixes some conformance verbs;
- Modifies some conformance statements and sample XML for clarifications in Medications Entry;
- Fixes some attributes in Payer Section;
- Fixes some Xpaths and element names in constraints table;
- Adds and fixes some codes in Appendix A Code System Table;
- Fixes some conformance verbs and data element names in Appendix B ''Ambulatory Healthcare Provider Cancer Event Report—Data Elements'';
- Fixes value in value set; and
- Adds data elements for transmission of Grade and pathological TNM Stage.

These improvements are important to the IG and will continue to support interoperability. Given the improvements that will be included in the updated IG, we propose to adopt it (Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.1) at § 170.205(i)(2) for the 2015 Edition certification criterion for transmission to cancer registries at § 170.315(f)(6).

- Automated Numerator Recording

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(g)(1) (Automated numerator recording)
Gap Certification Status
Eligibility is Fact-Specific

We propose to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version.

- Automated Measure Calculation

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(g)(2) (Automated measure calculation)
Gap Certification Status
Eligibility is Fact-Specific

We propose to adopt a 2015 Edition ''automated measure calculation'' certification criterion that is the same as the 2014 Edition certification criterion. We propose to apply the guidance provided for the 2014 Edition ''automated measure calculation'' certification criterion in the 2014 Edition Final Rule in that EHR technology must be able to support all CMS-acceptable approaches for measuring a numerator and denominator in order for to meet the proposed 2015 Edition ''automated measure calculation'' certification criterion.[97] We also propose that the interpretation of the 2014 Edition ''automated measure calculation'' certification criterion in FAQ 32 [98] would apply to the proposed 2015 Edition ''automated measure calculation'' certification criterion.

- Safety-Enhanced Design; and Quality Management System

MU Objective
N/A
2015 Edition EHR Certification Criteria
§ 170.315(g)(3) (Safety-Enhanced Design)
§ 170.315(g)(4) (Quality Management System)
Gap Certification Status
Eligibility is Fact-Specific—Safety-Enhanced Design
Eligible—Quality Management System

We propose to adopt 2015 Edition EHR certification criteria that are the same as the 2014 Edition versions, but solicit public comment regarding whether we should modify these criteria in light of feedback that we received during the HITPC ''Implementation and Usability'' hearing on July 23, 2013.[99] Specifically, we request comment regarding:

- Whether the scope of ''Safety-Enhanced Design'' should be expanded to include additional certification criteria;
- Whether formative usability tests should be explicitly required, or used as substitutes for summative testing;
- Whether there are explicit usability tests that should be required in addition to summative testing; and
- Whether there should be a minimum number of test subjects explicitly required for usability testing.

We note that we have updated the cross referencing in the 2015 Edition version of the ''safety-enhanced design'' certification criterion to track the updated certification criteria paragraph numbering.

- Non-Percentage-Based Measures Report

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(g)(5) (Non-percentage-based measures report)
Gap Certification Status
Ineligible

We propose to adopt a new certification criterion in the 2015 Edition entitled ''non-percentage-based measures report.'' Specifically, we propose to adopt a new 2015 Edition EHR certification criterion at § 170.315(g)(5) that would apply to EHR technology presented for certification that includes certain ''non-percentage-based capabilities'' (i.e., capabilities that support MU objectives for which the corresponding MU measure is not percentage-based). In the 2014 Edition NPRM (77 FR 13842), we proposed a certification criterion entitled ''non-percentage-based measure use report.'' This certification criterion was meant to complement the other certification

[95] *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0 (incorporated by reference in § 170.299).

[96] This IG will be available for review during the public comment period at *http://www.cdc.gov/EHRmeaningfuluse/guides.html.*

[97] 77 FR 54244–54245.

[98] *http://www.healthit.gov/policy-researchers-implementers/32-question-11-12-032.*

[99] *http://www.healthit.gov/archive?dir=FACA%20Hearings/2013-07-23%20Standards%3A%20Implementation%2C%20Meaningful%20Use%2C%20and%20Certification%20%26%20Adoption%20WGs%2C%20%20Implementation%20%26%20Usability%20Hearing.*

criteria we proposed to support the calculation of percentage-based MU measures. In the 2014 Edition Final Rule (77 FR 54186), we acknowledged commenters' concerns regarding the complexities raised by our proposed ''non-percentage-based measure use report'' certification criterion and that additional specificity would be needed to make the certification criterion more effective. Although we declined to adopt the proposed certification criterion in the final rule, we affirmed our belief in its spirit and direction—that EPs, EHs, and CAHs would benefit from EHR technology that could electronically report non-percentage-based MU objectives and measures.

In November 2012, the HITPC issued a Request for Comment (RFC) regarding potential meaningful use Stage 3 recommendations.[100] The RFC specifically solicited feedback on ways in which EHR technology could help providers document the use of EHR technology capabilities associated with MU measures that are not percentage-based. The comments submitted in response to the RFC as well as the 2014 Edition NPRM echoed the need for EHR technology to be able to assist providers document their use of EHR technology to achieve non-percentage-based objectives and measures. The comments also confirmed and have sharpened our understanding of the complexities associated with this type of certification criterion. Further, we considered these comments in light of the recommendation from the HHS OIG that, ''where possible,'' ONC require that certified EHR technology be capable of producing reports for all MU measures, including non-percentage-based measures.[101] OIG explained that such reports could help EPs, EHs, and CAHs prove compliance in the event of an audit and simplify CMS' oversight of the EHR Incentive Programs by allowing CMS to conclusively verify that an EP, EH, or CAH had relevant EHR technology capabilities in use during their reporting period. OIG also acknowledged that producing reports may not be possible for some measures.

The new criterion we propose to adopt is more specific than the one we proposed in the 2014 Edition NPRM and also clarifies key aspects of the 2014 Edition proposal that caused confusion. Specifically, this proposed criterion recognizes that certain aspects of ''use'' associated with non-percentage-based measures will occur in different ways based on the particular EHR technology capability involved. In that regard, the proposed criterion provides EHR technology developers with substantial flexibility to create innovative approaches to document evidence of use and because non-percentage-based MU measures vary, we do not presume that there is one particular way to meet this certification criterion.

The proposed certification criterion would require that an EHR technology presented for certification be capable of electronically generating a report that shows a user had used (or interacted with) the EHR technology capability associated with a non-percentage-based MU measure during an EHR reporting period. This means that, at a minimum, the EHR technology would need to be capable of determining an EHR reporting period (date range) and be able to record some evidence of use (e.g., transaction, user action, intervention/reminder) during the reporting period. We request public comment on whether we should make the regulatory text for this certification criterion more specific or if we should maintain the word ''evidence'' and use the final rule's preamble to provide more examples of what evidence would be acceptable (if we determine to adopt this criterion). If we were to make the regulatory text more specific, we propose these two options, but also solicit comment on other potential language that would make satisfying this criterion clearer.

- *Option 1:* Require the EHR technology to record evidence of use each time a particular capability was used during the reporting period.
- *Option 2:* Require the EHR technology to record evidence of use at the beginning, during, and end of the reporting period.

In some cases we understand that it will not be possible for EHR technology to record whether a non-percentage-based capability was used ''to demonstrate MU'' because this determination depends on the context in which the use of the capability occurred or on other subjective factors that cannot be determined through EHR technology use. To address this point, the proposed criterion focuses on the ability of EHR technology to record pertinent information about the use of non-percentage-based capabilities (e.g., transaction, user action, intervention/reminder) that would be helpful to ascertain whether the corresponding MU measure was met during a reporting period. Moreover, as indicated in Table 2 and explained below, the proposed criterion would apply to only those non-percentage-based measures for which this pertinent information would be available to the EHR technology based on the nature of the capabilities and the ways in which a user could be expected to interact with them. To note, the use of the term ''unchanged'' in the ''MU Stage 2'' column of the table denotes that the objective and/or measure has not changed from MU Stage 1.

TABLE 2—2015 EDITION CERTIFICATION CRITERIA THAT SUPPORT ONE OR MORE NON-PERCENTAGE-BASED MEASURES

Applicable	Certification criterion	MU Stage 1*	MU Stage 2*
Y	§ 170.315(a)(4), Drug-drug, drug-allergy interaction checks.	*Objective.* Drug-drug, drug-allergy interaction checks. *Measure.* Enable the functionality for the entire EHR reporting period	*Objective.* Clinical decision support. *Measure.* Enable and implement drug-drug and drug-allergy interaction checks *and* implement five CDS interventions for at least four CQMs for the entire reporting period.
Y	§ 170.315(a)(10), Clinical decision support	*Objective.* Clinical decision support *Measure.* Implement one clinical decision support rule	
Y	§ 170.315(a)(16), Patient list creation	*Objective.* Patient lists *Measure* Generate at least 1 report listing patients with a specific condition	*Objective.* Unchanged. *Measure.* Unchanged.

[100] The Request for Comments is available at *http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf.*

[101] OEI–05–11–00250 (Nov. 2012), available at *https://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf.*

TABLE 2—2015 EDITION CERTIFICATION CRITERIA THAT SUPPORT ONE OR MORE NON-PERCENTAGE-BASED MEASURES—Continued

Applicable	Certification criterion	MU Stage 1*	MU Stage 2*
Y	§ 170.315(f)(2), Transmission to immunization registries.	*Objective.* Transmission to immunization registries. *Measure.* Perform a test and follow-up submission if the test was successful	*Objective.* Unchanged. *Measure.* Successful ongoing submission from CEHRT for entire reporting period.
Y	§ 170.315(f)(3), Transmission to public health agencies (surveillance).	*Objective.* Transmission to public health agencies (syndromic surveillance data). *Measure.* Perform a test and follow-up submission if the test was successful	*Objective.* Unchanged. *Measure.* Successful ongoing submission for entire reporting period.
Y	§ 170.315(f)(4), Transmission of reportable laboratory tests and values/results.	*Objective.* Transmission to public health agencies (reportable lab data). *Measure.* Perform a test and follow-up submission if the test was successful	*Objective.* Unchanged. *Measure.* Successful ongoing submission for entire reporting period.
	§ 170.315(f)(6), Transmission to cancer registries.	N/A	*Objective.* Capability to identify and report cancer cases to a State cancer registry. *Measure.* Successful ongoing submission for entire reporting period.
N	§ 170.315(b)(1), Transitions of care	*Objective.* Transitions of care *Measure.* Provides a summary of care record for more than 50% of transitions of care and referrals	*Objective.* Transitions of care. *Measures.* (1) Provide a summary of care record for more than 50% of transitions of care and referrals. (2) Provide a summary of care record electronically for more than 10% of transitions of care and referrals. (3)(A) Conducts one or more successful electronic exchanges of a summary of care record with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's; or (B) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.
N	§ 170.315(a)(12), Drug-formulary checks	*Objective.* Implement drug-formulary checks. *Measure.* Enable functionality and have access to one internal or external formulary for entire reporting period	*Objective.* Generate and transmit permissible prescriptions electronically (eRx). *Measure.* More than 50% of prescriptions (EP) or more than 10% of hospital discharge medication orders for permissible prescriptions (EH/CAH) are queried for a drug-formulary and transmitted electronically using CEHRT.
N	§ 170.315(d)(1)–(9), Privacy and Security	*Objective.* Protect electronic health information through implementation of appropriate technical capabilities. *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of the EP's, EH's, or CAH's risk management process	*Objective.* Unchanged. *Measure.* Unchanged.

*The requirements for each meaningful use objective and measure are set forth in 42 CFR § 495.6. For convenience, we have summarized and/or condensed the descriptions for each objective and measure listed in the table above.

We propose *not* to include within the scope of this certification criterion the EHR technology capability specified in § 170.315(a)(12), which supports the MU Stage 1 objective ''Implement drug-formulary checks'' and the associated non-percentage-based measure. This objective was merged with the new MU Stage 2 objectives ''Generate and transmit permissible prescriptions electronically (eRx)'' for EPs and ''Generate and transmit permissible discharge prescriptions electronically (eRx)'' for EHs and CAHs, each of which is associated with a new percentage-based measure. As a result, EHR technology certified to § 170.315(a)(12) must also be certified to the ''automated numerator recording'' or ''automated measure recording'' certification criterion and will provide adequate evidence of use with respect to MU Stage 1 measure related to drug-formulary checks.

We also propose to treat the proposed ToC capability specified at § 170.315(b)(1) as inapplicable for purposes of this proposed certification criterion. The corresponding MU Stage 1 measure for this capability is percentage-based. The corresponding MU Stage 2 objective has three measures, two of which are percentage-based. The third measure is non-percentage-based, but involves one or more discrete transactions in which the EHR user will either receive some form of confirmation (from the CMS-designated test EHR) or the transaction is documented by the EP, EH, or CAH.

Finally, as we previously stated in the 2014 Edition Final Rule, the privacy and

security certification criteria proposed for adoption in § 170.315(d), which are associated with the MU objective (and measure) entitled ''protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities,'' would not be included within the scope of this certification criterion because we do not believe that EHR technology would be able to capture that a security risk analysis was performed by an EP, EH, or CAH except through a manual entry by the EP, EH, or CAH affirming the completion of the risk analysis.

Consistent with the way in which we have previously implemented certification policy that more generally applies to EHR technology, an ONC–ACB would also need to have new certification responsibilities if we were to adopt this proposed criterion in a final rule. As a result, we are also proposing to revise 45 CFR 170.550. This revision would ensure that EHR Modules presented for certification to certification criteria that support MU objectives with a non-percentage-based measure are certified to this certification criterion proposed at § 170.315(g)(5).

• Transmission Certification Criteria

As discussed in the proposed 2015 Edition ToC certification criterion earlier in this preamble, we have determined that it would best support industry interoperability approaches and provider choices for electronic exchange services if we permitted ''data content'' capabilities to be tested and certified separately from ''data transmission'' capabilities. As a result, we propose below three 2015 Edition transmission certification criteria that reflect the decoupling of content and transport from both the ToC certification criterion and VDT certification criterion. These three proposed criteria mirror the transmission standards listed in the 2014 Edition ToC certification criterion with the first at 170.315(h)(1) mirroring the same transmission standard list in the 2014 Edition VDT certification criterion. We have not proposed to require the ability to receive Consolidated CDAs transmitted in accordance with the IG for Direct Edge Protocols in these certification criteria because we believe it to be unnecessary to require as a condition of certification. We assume that: 1) it will be in the best/market interests of any EHR technology developer who gets a product separately certified to any of these certification criteria to ensure that the product is able to receive data from EHR technology certified to electronically transmit in accordance with the IG for Direct Edge Protocols (otherwise its product's viability and competitiveness on the market would be limited); and 2) it would be redundant in cases where a single EHR technology is certified to, for example, both the proposed 2015 Edition ToC certification criterion at § 170.315(b)(1) and the Transmit—Applicability Statement for Secure Health Transport at § 170.315(h)(1). However, we solicit comment on whether there are other factors we have not considered in coming to these conclusions.

• Transmit—Applicability Statement for Secure Health Transport

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(h)(1) (Transmit—Applicability Statement for Secure Health Transport)
Gap Certification Status
Ineligible

We propose to adopt a new 2015 Edition certification criterion for electronic transmission at 45 CFR 170.315(h)(1) that would enable EHR technology to be tested and certified solely to perform transmissions in accordance with the Applicability Statement for Secure Health Transport (the primary Direct Project specification) adopted at § 170.202(a). We expect that this capability would be tested similarly to how it is today except that only this capability would be tested.

• Transmit—Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(h)(2) (Transmit—Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging)
Gap Certification Status
Ineligible

We propose to adopt a new 2015 Edition certification criterion for electronic transmission at 45 CFR 170.315(h)(2) that would enable EHR technology to be tested and certified solely to perform transmissions in accordance with the Applicability Statement for Secure Health Transport (the primary Direct Project specification) adopted at § 170.202(a) and its companion specification XDR and XDM for Direct Messaging Specification adopted at § 170.202(b). We expect that this capability would be tested similarly to how it is today except that only this capability would be tested.

• Transmit—SOAP Transport and Security Specification and XDR/XDM for Direct Messaging

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(h)(3) (Transmit—SOAP Transport and Security Specification and XDR/XDM for Direct Messaging)
Gap Certification Status
Ineligible

We propose to adopt a new 2015 Edition certification criterion for electronic transmission at 45 CFR 170.315(h)(3) that would enable EHR technology to be tested and certified solely to perform transmissions in accordance with the Transport and Security Specification (also referred to as the SOAP-Based Secure Transport RTM adopted at § 170.202(c) and its companion specification XDR and XDM for Direct Messaging Specification adopted at § 170.202(b). We expect that this capability would be tested similarly to how it is today except that only this capability would be tested.

• Transmit—Applicability Statement for Secure Health Transport and Delivery Notification in Direct

MU Objective
N/A
2015 Edition EHR Certification Criterion
§ 170.315(h)(4) (Transmit—Applicability Statement for Secure Health Transport and Delivery Notification in Direct)
Gap Certification Status
Ineligible

We propose to adopt a new 2015 Edition certification criterion for electronic transmission at 45 CFR 170.315(h)(4) that would enable EHR technology to be tested and certified solely to perform transmissions in accordance with the Applicability Statement for Secure Health Transport (the primary Direct Project specification) adopted at § 170.202(a) and its companion specification Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012 (Delivery Notification IG).[102] The primary Direct Project specification requires that Security/Trust Agents (STAs) must issue a Message Disposition Notification (MDN, RFC3798) with a disposition of processed upon successful receipt, decryption, and trust validation of a Direct message. By sending this MDN, the receiving STA is taking

[102] *http://wiki.directproject.org/file/view/Implementation+Guide+for+Delivery+Notification+in+Direct+v1.0.pdf.*

custodianship of the message and is indicating that it will deliver the message to its destination. While the primary Direct Project specification indicates that additional MDNs may be sent to indicate further processing progress of the message, they are not required. The primary Direct Project specification, however, does *not* provide guidance in regards to the actions that should be taken by the sending STA in the event an MDN processed message is not received or if the receiving STA cannot deliver the message to its destination after sending the initial MDN processed message. Due to the lack of specifications and guidance in the primary Direct Project specification regarding deviations from normal message flow, STAs implementing only requirements denoted as ''must'' in Section 3 of the primary Direct Project specification may not be able to provide a high level of assurance that a message has arrived at its destination. The Delivery Notification IG provides implementation guidance enabling STAs to provide a high level of assurance that a message has arrived at its destination and outlines the various exception flows that result in compromised message delivery and the mitigation actions that should be taken by STAs to provide success and failure notifications to the sending system.

From a CLIA regulations perspective, the Delivery Notification IG can provide the necessary level of assurance that sent laboratory results are received by a provider. Additionally, we note that the Delivery Notification IG could be generally useful for any transmission that requires a high level of assurance.

Finally, given that testing and certification to this certification criterion would assess conformance to specific, distinct capabilities, we propose that certification to § 170.315(h)(4) would not satisfy § 170.315(h)(1) or (h)(2), which would need to be separately demonstrated to pass testing and certification.

B. 2014 Edition to 2015 Edition Equivalency Table

The following table identifies the proposed 2015 Edition EHR certification criteria that are equivalent to the 2014 Edition certification criteria for the purposes of meeting the CEHRT definition.

TABLE 3—2015 EDITION TO 2014 EDITION EQUIVALENCY

2015 Edition		2014 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
§ 170.315(a)(4)	Drug-drug, drug-allergy interaction checks	§ 170.314(a)(2)	Drug-drug, drug-allergy interaction checks.
§ 170.315(a)(5)	Demographics	§ 170.314(a)(3)	Demographics.
§ 170.315(a)(6)	Vital signs, BMI, & growth charts	§ 170.314(a)(4)	Vital signs, BMI, & growth charts.
§ 170.315(a)(7)	Problem list	§ 170.314(a)(5)	Problem list.
§ 170.315(a)(8)	Medication list	§ 170.314(a)(6)	Medication list.
§ 170.315(a)(9)	Medication allergy list	§ 170.314(a)(7)	Medication allergy list.
§ 170.315(a)(10)	Clinical decision support	§ 170.314(a)(8)	Clinical decision support.
§ 170.315(a)(11)	Electronic notes	§ 170.314(a)(9)	Electronic notes.
§ 170.315(a)(12)	Drug-formulary checks	§ 170.314(a)(10)	Drug-formulary checks.
§ 170.315(a)(13)	Smoking status	§ 170.314(a)(11)	Smoking status.
§ 170.315(a)(14)	Image results	§ 170.314(a)(12)	Image results.
§ 170.315(a)(15)	Family health history	§ 170.314(a)(13)	Family health history.
§ 170.315(a)(16)	Patient list creation	§ 170.314(a)(14)	Patient list creation.
§ 170.315(a)(17)	Patient-specific education resources	§ 170.314(a)(15)	Patient-specific education resources.
§ 170.315(a)(18)	Electronic medication administration record	§ 170.314(a)(16)	Electronic medication administration record.
§ 170.315(a)(19)	Advance directives	§ 170.314(a)(17)	Advance directives.
§ 170.315(b)(2)	Clinical information reconciliation and incorporation.	§ 170.314(b)(4)	Clinical information reconciliation.
§ 170.315(b)(3)	Electronic prescribing	§ 170.314(b)(3)	Electronic prescribing.
§ 170.315(b)(4)	Incorporate lab tests & values/results	§ 170.314(b)(5)	Incorporate lab tests & values/results.
§ 170.315(b)(5)	Transmission of electronic lab tests & values/results to ambulatory providers.	§ 170.314(b)(6)	Transmission of electronic lab tests & values/results to ambulatory providers.
§ 170.315(b)(6)	Data portability	§ 170.314(b)(7)	Data portability.
§ 170.315(c)(1)–(3)	Clinical quality measures	§ 170.314(c)(1)–(3)	Clinical quality measures.
§ 170.315(d)(1)	Authentication, access control, & authorization	§ 170.314(d)(1)	Authentication, access control, & authorization.
§ 170.315(d)(2)	Auditable events and tamper resistance	§ 170.314(d)(2)	Auditable events and tamper resistance.
§ 170.315(d)(3)	Audit report(s)	§ 170.314(d)(3)	Audit report(s).
§ 170.315(d)(4)	Amendments	§ 170.314(d)(4)	Amendments.
§ 170.315(d)(5)	Automatic log-off	§ 170.314(d)(5)	Automatic log-off.
§ 170.315(d)(6)	Emergency access	§ 170.314(d)(6)	Emergency access.
§ 170.315(d)(7)	End-user device encryption	§ 170.314(d)(7)	End-user device encryption.
§ 170.315(d)(8)	Integrity	§ 170.314(d)(8)	Integrity.
§ 170.315(d)(9)	Accounting of disclosures	§ 170.314(d)(9)	Accounting of disclosures.
§ 170.315(e)(1)	View, download, & transmit to 3rd party	§ 170.314(e)(1)	View, download, & transmit to 3rd party.
§ 170.315(e)(2)	Clinical summary	§ 170.314(e)(2)	Clinical summary.
§ 170.315(e)(3)	Secure messaging	§ 170.314(e)(3)	Secure messaging.
§ 170.315(f)(1) & (f)(2)	Immunization information/Transmission to immunization registries.	§ 170.314(f)(1) & (f)(2)	Immunization information/Transmission to immunization registries.
§ 170.315(f)(3)	Transmission to public health agencies—syndromic surveillance.	§ 170.314(f)(3)	Transmission to public health agencies—syndromic surveillance.
§ 170.315(f)(4)	Transmission of reportable lab tests & values/results.	§ 170.314(f)(4)	Transmission of reportable lab tests & values/results.
§ 170.315(f)(5)	Cancer case information	§ 170.314(f)(5)	Cancer case information.
§ 170.315(f)(6)	Transmission to cancer registries	§ 170.314(f)(6)	Transmission to cancer registries.
§ 170.315(g)(1)	Automated numerator recording	§ 170.314(g)(1)	Automated numerator recording.

TABLE 3—2015 EDITION TO 2014 EDITION EQUIVALENCY—Continued

2015 Edition		2014 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
§ 170.315(g)(2)	Automated measure calculation	§ 170.314(g)(2)	Automated measure calculation.
§ 170.315(g)(3)	Safety-enhanced design	§ 170.314(g)(3)	Safety-enhanced design.
§ 170.315(g)(4)	Quality management system	§ 170.314(g)(4)	Quality management system.

C. Gap Certification Eligibility Table for 2015 Edition EHR Certification Criteria

We define ''gap certification'' at 45 CFR 170.502 as ''the certification of a previously certified Complete EHR or EHR Module(s) to: (1) [a]ll applicable new and/or revised certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results of a NVLAP-accredited testing laboratory; and (2) [a]ll other applicable certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results used to previously certify the Complete EHR or EHR Module(s)'' (for further explanation, see 76 FR 1307–1308). Our gap certification policy focuses on the differences between certification criteria that are adopted through rulemaking at different points in time. This allows EHR technology to be certified to only the differences between certification criteria editions rather than requiring EHR technology to be fully retested and recertified to certification criteria that remain unchanged from one edition to the next and for which previously acquired test results are sufficient. Under our gap certification policy, ''unchanged'' criteria (see 77 FR 54248 for further explanation) are eligible for gap certification, and each ONC–ACB has discretion over whether it will provide the option of gap certification.

For the purposes of gap certification, Table 4 below provides a crosswalk of ''unchanged'' 2015 Edition EHR certification criteria to the corresponding 2014 Edition certification criteria. We note that with respect to the 2015 Edition certification criteria proposed for adoption at § 170.315(g)(1) through (g)(3) that gap certification eligibility for these criteria is fact-specific and will depend on any modifications made to the specific certification criteria to which these ''paragraph (g)'' certification criteria apply.

TABLE 4—GAP CERTIFICATION ELIGIBILITY FOR 2015 EDITION EHR CERTIFICATION CRITERIA

2015 Edition		2014 Edition	
Regulation section	Title of regulation paragraph	Regulation section	Title of regulation paragraph
§ 170.315(a)(1)	Computerized physician order entry—medications.	§ 170.314(a)(1)	Computerized Provider Order Entry.
§ 170.315(a)(3)	Computerized physician order entry—radiology/imaging..		
§ 170.315(a)(4)	Drug-drug, drug-allergy interaction checks.	§ 170.314(a)(2)	Drug-drug, drug-allergy interaction checks.
§ 170.315(a)(6)	Vital signs, BMI, & growth charts	§ 170.314(a)(4)	Vital signs, BMI, & growth charts.
§ 170.315(a)(7)	Problem list	§ 170.314(a)(5)	Problem list.
§ 170.315(a)(8)	Medication list	§ 170.314(a)(6)	Medication list.
§ 170.315(a)(9)	Medication allergy list	§ 170.314(a)(7)	Medication allergy list.
§ 170.315(a)(12)	Drug-formulary checks	§ 170.314(a)(10)	Drug-formulary checks.
§ 170.315(a)(13)	Smoking status	§ 170.314(a)(11)	Smoking status.
§ 170.315(a)(14)	Image results	§ 170.314(a)(12)	Image results.
§ 170.315(a)(16)	Patient list creation	§ 170.314(a)(14)	Patient list creation.
§ 170.315(a)(18)	Electronic medication administration record	§ 170.314(a)(16)	Electronic medication administration record.
§ 170.315(a)(19)	Advance directives	§ 170.314(a)(17)	Advance directives.
§ 170.315(b)(3)	Electronic prescribing	§ 170.314(b)(3)	Electronic prescribing.
§ 170.315(c)(1)–(3)	Clinical quality measures	§ 170.314(c)(1)–(3)	Clinical quality measures.
§ 170.315(d)(1)	Authentication, access control, & authorization	§ 170.314(d)(1)	Authentication, access control, & authorization.
§ 170.315(d)(3)	Audit report(s)	§ 170.314(d)(3)	Audit report(s).
§ 170.315(d)(4)	Amendments	§ 170.314(d)(4)	Amendments.
§ 170.315(d)(5)	Automatic log-off	§ 170.314(d)(5)	Automatic log-off.
§ 170.315(d)(6)	Emergency access	§ 170.314(d)(6)	Emergency access.
§ 170.315(d)(7)	End-user device encryption	§ 170.314(d)(7)	End-user device encryption.
§ 170.315(d)(8)	Integrity	§ 170.314(d)(8)	Integrity.
§ 170.315(d)(9)	Accounting of disclosures	§ 170.314(d)(9)	Accounting of disclosures.
§ 170.315(e)(3)	Secure messaging	§ 170.314(e)(3)	Secure messaging.
§ 170.315(f)(1)	Immunization information	§ 170.314(f)(1)	Immunization information.
§ 170.315(f)(3)#	Transmission to public health agencies—syndromic surveillance.	§ 170.314(f)(3)#	Transmission to public health agencies—syndromic surveillance
§ 170.315(f)(5)	Cancer case information	§ 170.314(f)(5)	Cancer case information.
§ 170.315(g)(4)	Quality management system	§ 170.314(g)(4)	Quality management system.

If certified to the revised 2014 Edition version of this criterion after the effective date of the 2015 Edition Final Rule. For further information on this distinction, please see the gap certification discussion under the ''Transmission to Public Health Agencies—Syndromic Surveillance'' in section III.A of this preamble.

D. HIT Definitions

1. CEHRT and Base EHR Definitions

We propose revisions to the CEHRT and Base EHR definitions at § 170.102 for the purpose of including the proposed 2015 Edition EHR certification criteria in those definitions.

We propose to revise the CEHRT definition for FY/CY 2014 and subsequent years to include reference to the 2015 Edition EHR certification criteria. Under our proposal, EPs, EHs, and CAHs would have the flexibility to use EHR technology that has been certified to either the 2014 Edition or the 2015 Edition, or a combination of both editions, to meet the CEHRT definition for FY/CY 2014 and subsequent years. We believe this proposal would enhance the already flexible CEHRT definition available to EPs, EHs, and CAHs by enabling them to use EHR technology certified to the 2015 Edition to meet the CEHRT definition and would permit an incremental transition from the adoption and implementation of EHR technology certified from one edition of EHR certification criteria to another.

We propose to include in the Base EHR definition the 2015 Edition EHR certification criteria that correspond to the 2014 Edition EHR certification criteria already specified in the Base EHR definition (i.e., CPOE, demographics, problem list, medication list, medication allergy list, CDS, CQMs, transitions of care, data portability, and privacy and security). Our proposed changes to the Base EHR definition would permit EPs, EHs, and CAHs to meet the Base EHR definition with EHR technology certified to either the 2014 Edition or the 2015 Edition, or a combination of both. With the 2014 Edition, EHR technology developers have the ability to market their EHR technology as meeting the Base EHR definition when appropriate. We would continue this policy upon the adoption of the 2015 Edition EHR certification criteria.

2. Complete EHR

We propose to discontinue use of the Complete EHR definition as a regulatory concept beginning with the 2015 Edition EHR certification criteria. Currently, there are definitions for ''Complete EHR, 2011 Edition'' and ''Complete EHR, 2014 Edition'' under § 170.102. However, under our proposal, we would not add a new definition for ''Complete EHR, 2015 Edition.'' As a result, ONC–ACBs would not be able to issue Complete EHR certifications to EHR technology certified to the 2015 Edition EHR certification criteria. Despite adopting a revised, more flexible, CEHRT definition in the 2014 Edition Final Rule that permits EPs, EHs, and CAHs to use (if available) EHR Modules certified to the minimum number of certification criteria necessary to support their achievement of the specific MU Stage they needed to meet, we maintained the Complete EHR concept and Complete EHR certification to the 2014 Edition. We assumed some EPs, EHs, and CAHs might prefer the relative simplicity a Complete EHR certification offered from a regulatory compliance perspective compared to the flexibility and responsibility offered by an EHR Module(s) approach to the new CEHRT definition. While we thought the continued availability of Complete EHR certifications would be helpful for some EPs, EHs, and CAHs, we did not believe that for the 2014 Edition the use of Complete EHRs would be the primary way the CEHRT definition would be met because the revised, more flexible, CEHRT definition adopted in the 2014 Edition Final Rule permitted EPs, EHs and CAHs to have less than a certified Complete EHR to meet the CEHRT definition. We believe this proposed rule serves as an ideal time to propose discontinuing the Complete EHR concept beginning with the 2015 Edition and before we propose the 2017 Edition.

The following explains our rationale for discontinuing the Complete EHR concept beginning with the 2015 Edition:

(1) The Complete EHR definition initially was intended to support the original CEHRT definition established in the 2011 Edition Final Rule under § 170.102. As a general summary, the original CEHRT definition required an EP, EH, and CAH to have EHR technology that met *ALL* of the certification criteria adopted for an applicable setting (ambulatory or inpatient). The ''Complete EHR'' term and definition was meant to convey that all applicable certification criteria had been met and the statutory requirements of the Qualified EHR definition had been fulfilled. As noted above, the current CEHRT definition and Complete EHR definition no longer share the same symmetry. In fact, the 2014 Edition Complete EHR definition now exceeds the CEHRT definition's requirements as to the number of certification criteria to which an EHR technology would need to be certified to meet the CEHRT definition.

(2) Since publication of the 2014 Edition Final Rule, we have received stakeholder feedback through email questions and during educational presentations and other outreach that demonstrates confusion about the interplay between the CEHRT definition, the Base EHR definition (adopted as part of the 2014 Edition Final Rule), and the Complete EHR definition. Stakeholders have correctly concluded that a certified 2014 Edition Complete EHR could be used to meet the CEHRT definition, but some believe incorrectly that their only regulatory option to meet the CEHRT definition is to adopt a certified Complete EHR. Even though, under the CEHRT definition for FY/CY 2014 and subsequent years in § 170.102, they only need EHR technology (EHR Modules) certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition (a finite set of capabilities) and includes all other capabilities that are necessary to meet the objectives and measures and successfully report CQMs *for the MU Stage they are attempting to achieve.*

(3) A Complete EHR is not necessarily ''complete'' or sufficient when it comes to an EP's, EH's, or CAH's attempt to achieve MU. For example, based on the ''Complete EHR, 2014 Edition'' definition, it may not be certified to particular CQMs on which an EP intends to report and it may not have been certified to capabilities included in *optional* certification criteria that an EP needs for MU, such as the 2014 Edition cancer reporting certification criteria (§ 170.314(f)(5) and (6)). Thus, if we were to continue this policy approach, we believe this discrepancy would only grow and cause greater confusion over time.

(4) Stakeholder feedback to us since the 2014 Edition Final Rule (via conference and webinar question and answer sessions, public meetings, emails) and the data currently available on the CHPL indicates that some EHR technology developers have continued to seek only a 2014 Edition Complete EHR certification and, thus, only plan to offer a certified Complete EHR as a solution to customers. While we recognize EHR technology developers may choose to pursue various approaches for designing and marketing their products, we are in a position to modify our policy so that it does not encourage EHR technology developers to offer only a single certified solution. In general, we believe the decision to seek certification only for a Complete EHR serves to defeat the flexibility provided by the ''new'' CEHRT definition. Consequently, by discontinuing the availability of the Complete EHR certification, the EHR technology market could be driven by EHR technology developers competing based more on the capabilities included

in their EHR technology than on the type of certification issued (Complete EHR or EHR Module).

(5) The discrepancy between what any single EP, EH, or CAH needs to achieve MU and the Complete EHR definition will likely only grow more disparate when we adopt certification criteria in a 2017 Edition rulemaking to support MU Stage 3. At that time, there may be EPs, EHs, and CAHs attempting to achieve each of the three stages of MU, but a Complete EHR in line with the current definition would likely include capabilities that support core and menu objectives and measures for all MU stages.

(6) Discontinuing the use of the Complete EHR concept would be consistent with the instruction of Executive Order (EO) 13563 to identify and consider approaches that make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives. To illustrate, we would not need to designate EHR certification criteria as mandatory or optional in our regulation text as these categories were specifically developed to accommodate the Complete EHR definition (i.e., cases where EHR technology would otherwise have to be certified to a criterion solely because it is required in order to satisfy the Complete EHR certification).

We welcome comments on our proposal to discontinue use of the Complete EHR concept beginning with the 2015 Edition. We emphasize that this proposal would have no impact on current 2014 Edition Complete EHR certifications or in using a 2014 Edition Complete EHR to meet the current CEHRT definition. Further, this proposal would not require EHR Module certification to only a specific set of certification criteria nor would it change what an EHR developer could present for EHR Module certification (e.g., EHR technology developed to meet all the certification criteria adopted for the ambulatory or inpatient setting could be presented for certification as an EHR Module). As an alternative to the proposal, if we were to keep the Complete EHR concept and definition for the 2015 Edition, we propose and seek comment on the following two approaches:

- Continue the same policy of adopting an edition-specific Complete EHR (e.g., 2015 Edition Complete EHR). In addition to the significant drawbacks discussed above that come with keeping the Complete EHR definition, this approach would also be inefficient because it would continue the need for regular regulatory changes, including adopting new edition-specific Complete EHR definitions and making changes to the Base EHR definition to accommodate various editions of Complete EHRs.
- Define a Complete EHR as ''EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of EHR certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting and meets the Base EHR definition.'' ONC–ACBs would be responsible for issuing Complete EHR certifications that specify the edition the Complete EHR was certified to. For example, EHR technology certified as a Complete EHR to the 2015 Edition would then be issued a certification that specifies that it is a 2015 Edition Complete EHR. This would also be evident through listing on the CHPL. This approach remains consistent with the policies we set forth in the 2014 Edition Final Rule that specify that a certification *cannot* be issued for a Complete EHR based on a combination of editions of EHR certification criteria and that certification must specify what edition an EHR technology is compliant with.

3. Common MU Data Set

We propose to change to the ''Common MU Data Set'' definition in § 170.102 to accommodate our proposed change to the preferred language standard as discussed earlier in this preamble under the 2015 Edition ''demographics'' certification criterion (§ 170.315(a)(5)). This proposal would not change the preferred language standard identified in the ''Common MU Data Set'' definition for certification to the 2014 Edition EHR certification criteria (i.e., ISO 639–2 constrained by ISO 639–1). Our proposed change to the ''Common MU Data Set'' definition will only affect certification to the 2015 Edition EHR certification criteria that reference the ''Common MU Data Set.'' Stated another way, for certification to these certification criteria under the 2015 Edition, EHR technology would need to meet the preferred language standard we eventually adopt in a subsequent final rule.

4. Cross Referenced FDA Definitions

As discussed in our proposal for the 2015 Edition ''implantable device list'' certification criterion, we propose to adopt in § 170.102 new definitions for ''Implantable Device,'' ''Unique Device Identifier,'' ''Device Identifier,'' and ''Production Identifier.'' We propose to adopt the same definitions already provided to these phrases at 21 CFR 801.3. Again, we believe adopting these definitions in our rule will prevent any interpretation ambiguity and ensure that each phrase's specific meaning reflects the same meaning given to them in the Unique Device Identification System Final Rule at in 21 CFR 801.3. Capitalization was purposefully applied to each word in these defined phrases in order to signal to readers that they have specific meanings.

IV. Provisions of the Proposed Rule Affecting the ONC HIT Certification Program

A. Applicability

We propose to revise the ''applicability'' section (§ 170.501) for the ONC HIT Certification Program to clearly indicate that references to the term Complete EHR and Complete EHR certification *do not* apply to certification in accordance with the 2015 Edition EHR certification criteria and any subsequent edition of certification criteria adopted by the Secretary under subpart C. This proposal is consistent with our proposal to discontinue the use of the term ''Complete EHR'' and Complete EHR certification beginning with the 2015 Edition EHR certification criteria as discussed under the section entitled ''Complete EHR'' of this preamble.

B. Non-MU EHR Technology Certification

Certification to the 2014 Edition and proposed 2015 Edition ''automated numerator recording'' certification criteria (§§ 170.314(g)(1) and 170.315(g)(1)) and the ''automated measure calculation'' certification criteria (§§ 170.314(g)(2) and 170.315(g)(2)) are important to ensure that EPs, EHs, and CAHs have efficient and accurate means for recording, calculating and reporting data for MU attestation. Therefore, we have taken steps to ensure EHR technology has these necessary capabilities by including certification requirements in § 170.550(f)(1) for EHR Modules that are certified to the 2014 Edition and proposing similar requirements in § 170.550(g) for EHR Modules that would be certified to the 2015 Edition, including requirements for certification to proposed § 170.315(g)(5) (''non-percentage-based measure report''). While these regulatory requirements are intended to provide assurance that EHR Modules can support EPs', EHs', and CAHs' MU attestation needs, they preclude the efficient certification of EHR technology designed for purposes other than achieving MU.

For example, EHR technology is often designed for other types of health care settings where individual or

institutional health care providers are not typically eligible to qualify for MU incentive payments under Medicare or Medicaid, such as behavioral health or long-term post-acute care settings. EHR technology is also designed, for example, primarily to support HIE and without regard for whether the health care provider using the technology seeks to achieve MU. In these examples, a developer could choose to present the EHR technology for certification as an EHR Module under the ONC HIT Certification Program for various reasons, such as if certification were to be required by another HHS program, or simply for the assurances that certification provides. However, if those EHR technologies were to be certified as 2014 Edition EHR Modules under the ONC HIT Certification Program in accordance with the existing regulations, they would be subject to the requirements of § 170.550(f)(1). In other words, EHR technology developers would be required to design their EHR technology to include specific capabilities related to MU measure recording, calculation, and reporting, even though the EHR technology would not be intended for MU.

We want to avoid such situations and instead make our regulatory structure more flexible and extensible such that it can more easily accommodate health IT certification for other purposes beyond MU. Additionally, we seek to ensure that under the ONC HIT Certification Program there is a clear distinction between EHR technology certified to support MU attestation requirements and EHR technology that is not. This distinction is important so that purchasers can more easily compare and select EHR technology that meets their needs. We propose to address these issues, starting with EHR technology that is certified to the 2015 Edition, by:

- Establishing an ''MU EHR Module'' definition and a ''non-MU EHR Module'' definition under the main ''EHR Module'' definition at § 170.102. An ''MU EHR Module'' would be defined as any service, component, or combination thereof *that is designed for purposes of the EHR Incentive Programs* and can meet the requirements of at least one certification criterion adopted by the Secretary. A ''non-MU EHR Module'' would be defined as any service, component, or combination thereof that is designed *for any purpose other than* the EHR Incentive Programs and can meet the requirements of at least one certification criterion adopted by the Secretary.
- Revising § 170.550 to require the certification of only MU EHR Modules, as applicable, to the proposed 2015 Edition ''automated numerator recording'' certification criterion (§ 170.315(g)(1)), the ''automated measure calculation'' certification criterion (§ 170.315(g)(2)), and the ''non-percentage-based measure use report'' certification criterion (§ 170.315(g)(5)). This proposal would ensure that EHR technology designed for MU purposes and certified to certification criteria that include capabilities that support percentage-based and/or non-percentage-based MU measures are capable of electronically performing the associated recording and calculation of measure activities for MU purposes.
- Requiring both MU EHR Modules and Non-MU EHR Modules to be certified, as applicable, to § 170.315(g)(3) (Safety-enhanced design) and/or (g)(4) (Quality system management). These proposed requirements can be found in § 170.550(g)(2) and (3), respectively, and maintain the policy approach established with certification to the 2014 Edition (see § 170.550(f)(2) and (3)) that ensures all EHR Modules are certified to these specific safety and quality certification criteria, as appropriate.
- Revising § 170.523(k)(1)(iii) to make clear that beginning with certifications issued to the 2015 Edition, the requirement in that section would only apply to MU EHR Modules. For EHR technology certified to the 2014 Edition, § 170.523(k)(1)(iii) continues to apply to Complete EHRs and all EHR Modules. We further note that we are not proposing to revise § 170.523(k)(1)(i) to require a EHR Module developer to state whether its 2015 Edition EHR Module is ''MU'' or ''non-MU'' on its Web site nor in any marketing materials, communications statements, and other assertions related to the EHR Module's certification. An EHR Module developer must still list the certification criteria that the EHR Module was certified to per § 170.523(k)(1)(ii). We also anticipate some form of distinct listing of MU and non-MU EHR Modules on the CHPL, as we expect ONC–ACBs will report whether the EHR Modules they certify to the 2015 Edition are MU EHR Modules or Non-MU EHR Modules. This is due to the fact that ONC–ACBs would have different certification responsibilities for MU EHR Modules and non-MU EHR Modules per proposed § 170.550(g). We believe these steps will be sufficient in providing market clarity.

We are not proposing to apply the certification concept of MU EHR Module and non-MU EHR Module to the 2014 Edition because of the inconsistency and potential confusion it would create regarding EHR Modules that have already been certified and, more importantly, because it would be infeasible to implement for the purposes of establishing a distinction on the CHPL in a timely manner to avoid such potential confusion. This decision is also in keeping with how we have handled prior changes to the certification of EHR technology. With the new requirements that we adopted for reporting test results hyperlinks and requiring price transparency related to MU, we only applied those requirements to EHR technology certified to the 2014 Edition and not the 2011 Edition.[103]

We wish to make clear that our proposed approach continues to leave EHR Module developers with discretion on how to develop and present their EHR technology for certification. We expect that an EHR Module developer would determine whether they want their EHR Module certified as a MU or non-MU EHR Module and then seek the appropriate testing and certification of their EHR Module from an accredited testing laboratory and an ONC–ACB, respectively. Our proposed approach would also *not* prevent MU EHR Modules from being sold or used for non-MU proposes since in theory a MU EHR Module could be used for non-MU purposes, although it would have certain MU-related capabilities (for example, automated numerator recording and automated measure calculation) that may be extraneous for some types of users or settings.

This proposal is based on our belief that EHR technology developers who design EHR technology for non-MU purposes and settings (e.g., broad electronic health information exchange or behavioral health settings staffed mainly by MU ineligibles) find the automated numerator and automated measure calculation certification criteria requirements as unnecessary burdens and resource investments (i.e., to have to program MU-specific rules into their software just to get certified). Similarly, we believe that because of the specific ways in which MU measures are structured non-MU health care providers would find little benefit in getting EHR utilization reports showing MU performance. Accordingly, we request public comment, particularly from EHR technology developers that design technology for non-MU purposes and settings and providers who use EHR technology for non-MU purposes or in non-MU settings, on whether:

[103] *http://www.healthit.gov/policy-researchers-implementers/26-question-10-12-026.*

• Our regulatory burden assumption is correct related to EHR technology developers having to meet the automated numerator and automated measure calculation certification criteria to obtain certification;

• The automated numerator and automated measure calculation certification criteria requirements pose more of burden for small EHR technology developers that design EHR technology for non-MU purposes and settings (e.g., inhibit their ability to compete with large EHR technology developers that have more resources to develop and get certified to the automated numerator and automated measure calculation certification criteria even if their customers will not use the capabilities); and

• Health care providers using EHR technology for non-MU purposes and settings would benefit from or be hindered by paying for and/or using EHR technology certified to the automated numerator and automated measure calculation certification criteria.

We also request comment on how best to implement our proposed approach if we were to adopt it in a subsequent final rule. In this regard, we request feedback on the following questions:

• Would the process for testing and certification be clear under our approach as described? Should EHR technology developers simply inform ONC–ACBs as to the type of EHR Module certification they seek (i.e., MU or non-MU)?

• How should we distinguish non-MU EHR Modules on the CHPL? Should we have separate listings of MU and non-MU EHR Modules? Are there other options?

• How should we indicate and list the availability of MU EHR Modules for use beyond MU purposes?

C. ONC Regulations FAQ 28

In ONC regulations FAQ 28,[104] we provide guidance on the application of § 170.314(g)(1) and (g)(2) to the certification of Complete EHRs and EHR Modules.

1. MU EHR Modules

We propose to apply the guidance expressed in FAQ 28 to the certification of MU EHR Modules to the 2015 Edition ''automated numerator recording'' certification criterion (§ 170.315(g)(1)) and the ''automated measure calculation'' certification criterion (§ 170.315(g)(2)). As we state in FAQ 28 and in the 2014 Edition Final Rule (77 FR 54186), ONC–ACBs can certify an EHR Module to either the 2014 Edition ''automated numerator recording'' certification criterion or the 2014 Edition ''automated measure calculation'' certification criterion. To provide regulatory clarity, we propose to revise § 170.550(f)(1) to specify this flexibility for the certification of EHR Modules to the 2014 Edition and propose the same flexibility in § 170.550(g)(1) for MU EHR Modules certified to the 2015 Edition.

Last, we also clarify that an EHR Module (or MU EHR Module, with regard to the 2015 Edition) could be certified to only the ''automated measure calculation'' certification criterion (§§ 170.314(g)(2) or proposed 170.315(g)(2)) in situations where the EHR Module does not include a capability that supports a percentage-based MU objective and measure, but can meet the requirements of the ''automated measure calculation'' certification criterion (§§ 170.314(g)(2) or proposed 170.315(g)(2)). An example of this would be an ''analytics'' EHR Module where data is fed from other EHR technology and the EHR Module can record the requisite numerators, denominators and create the necessary percentage report as specified in the ''automated measure calculation'' certification criterion. In these situations, § 170.550(f)(1) or (g)(1) would not be implicated or need to be applied.

2. Complete EHRs

We propose to revise § 170.314(g)(1) to be an optional certification criterion as a means of providing regulatory clarity for the certification of Complete EHRs to the 2014 Edition. This proposed revision implements our guidance provided in FAQ 28. In FAQ 28 we stated that EHR technology issued a 2014 Edition Complete EHR certification must be certified to § 170.314(g)(2) because it is a mandatory certification criterion consistent with the 2014 Edition Complete EHR definition requiring certification to all mandatory certification criteria for a particular setting (ambulatory or inpatient), but not § 170.314(g)(1) (even though it is currently designated as a mandatory certification criterion) because a 2014 Edition Complete EHR would have demonstrated capabilities beyond those included in § 170.314(g)(1) by being certified to (g)(2). Effectuating this proposal (to make § 170.314(g)(1) optional) would provide greater regulatory clarity for ONC–ACBs as they determine whether EHR technology meets the 2014 Edition Complete EHR definition.

As noted previously in this preamble, we propose to discontinue the use of the Complete EHR concept beginning with the 2015 Edition. If we were to retain the Complete EHR concept for the 2015 Edition, we propose to take the same approach for Complete EHRs as specified in FAQ 28 and in our proposed regulatory changes to § 170.314(g)(1). That is, Complete EHRs would need to be certified to the mandatory ''automated measure calculation'' certification criterion, but not the 2015 Edition ''automated numerator recording'' certification criterion as that would become an optional certification criterion.

D. Patient List Creation Certification Criteria

The 2014 Edition and proposed 2015 Edition ''patient list creation'' certification criteria (§ 170.314(a)(14) and § 170.315(a)(16), respectively) include capabilities that support two MU objectives, one with a percentage-based measure and one without (i.e., ''use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminders, per patient preference'' (''patient reminders'') and ''generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach,'' respectively). In situations where EHR technology is presented for certification to a ''patient list creation'' certification criterion (2014 or 2015 Edition) and does not include a capability to support ''patient reminders,'' we clarify it would not need to be certified to the ''automated numerator recording'' certification criterion (§§ 170.314(g)(1) for the 2014 Edition and 170.315(g)(1) for the 2015 Edition) nor the ''automated measure calculation'' certification criterion (§§ 170.314(g)(2) for the 2014 Edition and 170.315(g)(2) for the 2015 Edition) for ''patient reminders'' percentage-based measure capabilities.

E. ISO/IEC 17065

Section 170.503(b)(1) requires applicants for ONC-Approved Accreditor (ONC–AA) status to provide a detailed description of their experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (Guide 65). Section 170.503(e)(2) requires the ONC–AA to verify that the certification bodies it accredits and ONC–ACBs conform to, at a minimum, ISO/IEC Guide 65:1996. The International Organization for Standardization (ISO) has recently

[104] *http://www.healthit.gov/policy-researchers-implementers/28-question-11-12-028.*

issued ISO/IEC 17065: 2012 [105] (ISO 17065), which cancels and replaces Guide 65. The major changes that have been made as compared with Guide 65 are as follows:

- Restructuring this International Standard based on the common structure adopted by ISO/CASCO;
- Modifications based on ISO/PAS 17001, ISO/PAS 17002, ISO/PAS 17003, ISO/PAS 17004 and ISO/PAS 17005;
- Introduction of the ISO/IEC 17000 functional approach in the process requirements of Clause 7;
- Information on the application of this International Standard for processes and services in Annex B;
- Revision of the terms and definitions in Clause 3;
- Improvement of the impartiality requirements (mechanism);
- Consolidation of the management system requirements in Clause 8;
- Inclusion of principles for product certification bodies and their activities in Annex A;
- Improvement by taking into account IAF GD 5; and
- Inclusion of a reference to certification schemes, for which further information is provided in ISO/IEC 17067.

The current ONC–AA, American National Standards Institute (ANSI) has already notified the certification bodies it accredits that it will transition accreditation only to ISO 17065 and that all certification bodies it accredits should be accredited to ISO 17065 no later than September 15, 2015. Accordingly, because ISO has replaced Guide 65 with ISO/IEC 17065, we propose to revise § 170.503(b)(1) and (e)(2) to replace the references to Guide 65 with ISO 17065. For § 170.503(b)(1), the change would be effective as of the effective date of the 2015 Edition final rule that would follow this proposed rule. We anticipate that date would occur after we select an accreditation body as the ONC–AA for the next three-year term as ANSI's current term will expire in June 2014. As such, when we next need to assess applicants for ONC–AA status in early 2017, we would expect that any applicant will by then have experience evaluating the conformance of certification bodies to ISO 17065. For § 170.503(e)(2), we propose to require compliance with ISO 17065 beginning in FY 2016 (in other words, as of October 1, 2015). This compliance date should provide sufficient time for certification bodies that are interested in serving as ONC–ACBs, as well as existing ONC–ACBs, to be accredited to ISO 17065 by the ONC–AA. We welcome comments on these proposals.

We also propose to revise our references to ISO/IEC standards 17011, 17065 and Guide 65 in § 170.503 by removing or not including the date reference for each standard. The published date information for each standard will continue to be listed in § 170.599. This approach aligns with guidance from the Office of the Federal Register.

F. ONC Certification Mark

ONC has developed and administers the ''ONC Certified HIT'' certification and design mark (the ''Mark''). [106] The Mark, as used by an authorized user, certifies that a particular HIT product (Complete EHR, EHR Module, or other types of HIT for which the Secretary of HHS adopts applicable certification criteria, *see* 45 CFR 170.510) has been tested in accordance with test procedures approved by the National Coordinator; has been certified in accordance with the certification criteria adopted by the Secretary at 45 CFR 170, Subpart C; and has met all other required conditions of the ONC HIT Certification Program at 45 CFR 170, Subpart E.

We propose to require ONC–ACBs to use the Mark in connection with HIT they certify under the ONC HIT Certification Program. The required use of a singular identifying mark would provide consistency in the recognition of HIT certified under the ONC HIT Certification Program and mitigate any potential market confusion for purchasers of HIT products certified under the ONC HIT Certification Program. The required use of the Mark by all ONC–ACBs for products they certify under the ONC HIT Certification Program would offer more clarity and assurance to purchasers as compared to the use of separate and distinct marks by each ONC–ACB to indicate a product has been certified under the ONC HIT Certification Program. The required use of the Mark would also make clear that an HIT product was certified under the ONC HIT Certification Program versus another certification program for HIT (e.g., in cases where a certification body is both an ONC–ACB and administers other certification programs outside of the ONC HIT Certification Program).

We propose to revise § 170.523 (''Principles of Proper Conduct'') to require ONC–ACBs to display the Mark on all certifications issued under the ONC HIT Certification Program in a manner that complies with the Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark (''Terms of Use''). [107] In addition, we propose to revise § 170.523 to require ONC–ACBs to ensure that use of the Mark by HIT developers whose products are certified under the ONC HIT Certification Program is compliant with the Terms of Use. In the event that the Terms of Use are revised or updated, compliance with the most recent version would be required.

G. ''Certification Packages'' for EHR Modules

As we look toward the potential expansion of our certification program to support the various types of health care providers who are not eligible for EHR incentive payments under Medicare or Medicaid, we recognize that we can continue to improve the ease with which our regulatory concepts (for both MU and non-MU purposes) can be communicated to the general public and to EHR Module purchasers. In that regard, we believe it would be helpful to establish the concept of predefined ''certification packages'' that would reflect groupings of certification criteria. We intend for this concept to make it easier for stakeholders to communicate and understand the functionality an EHR Module includes and the certification criteria to which it is certified.

As explained below, we propose to:

(1) Identify subsets of certification criteria as ''certification packages,'' beginning with the 2015 Edition; and

(2) Require ONC–ACBs to ensure that EHR Module developers make accurate representations concerning certification packages on their Web sites and in marketing materials, communications statements, or other assertions related to an EHR Module's certification.

We propose and seek public comment on the following two certification packages: ''care coordination'' and ''patient engagement.'' We also seek comment on the specific certification criteria we have proposed to assign to those packages. As noted above, we propose that package designations would only be applicable to certifications issued to EHR Modules (MU and non-MU) certified to the 2015 Edition EHR certification criteria.

We propose to define ''certification package'' in § 170.502 as an identified set of certification criteria adopted by the Secretary in subpart C of part 170

[105] *http://www.iso.org/iso/catalogue_detail.htm?csnumber=46568*. ISO slide presentation on 17065: *http://www.iso.org/iso/ppt_presentation_17065.ppt*.

[106] *http://www.healthit.gov/policy-researchers-implementers/onc-hit-certification-program*.

[107] *http://www.healthit.gov/sites/default/files/hit_certificationterms_of_use_final.pdf*.

that represent a specific grouping of capabilities. We also propose definitions in § 170.502 for ''2015 Edition Care Coordination Package'' and ''2015 Edition Patient Engagement Package'' that each identify the set of specific certification criteria to which an EHR Module needs to be certified, at a minimum, in order for its EHR Module developer to represent that the EHR Module meets the requirements of a particular package.

• *Care Coordination Package:* This package would require an EHR Module to be certified to, at a minimum, the proposed 2015 Edition EHR certification criteria at § 170.315(b)(1) (Transitions of care); and § 170.315(b)(2) (Clinical information reconciliation and incorporation).

With respect to this package, we solicit comment on: (1) Whether we should also include § 170.315(h)(1) (Transmit—Applicability Statement for Secure Health Transport) in order to require that an EHR Module labeled with this package is also certified to the transmission certification criterion focused on the primary Direct Project specification; (2) whether it should be a more general requirement to be certified to any one of the § 170.315(h) transmission certification criteria (which could risk some organizations adopting an EHR Module labeled with ''care coordination package'' being unable to exchange with each other because their separate EHR Modules came with different transmission capabilities); (3) whether we should require that the EHR Module be certified to both § 170.315(h)(1) and § 170.315(h)(3) (i.e., ''Direct'' and SOAP); and (4) whether including any of the transmission criteria in § 170.315(h) as part of the package would recreate the same ''binding'' effect that we proposed to decouple earlier in this preamble (see the discussion of the ''Transitions of Care'' certification criterion in section III.A).

• *Patient Engagement Package:* This package would require an EHR Module to be certified to, at a minimum, the proposed 2015 Edition EHR certification criteria at § 170.315(e)(1) (View, download and transmit to a 3rd party); and § 170.315(e)(3) (Secure messaging).

With respect to this package, we solicit comment on whether we should include § 170.315(a)(16) (Patient list creation), § 170.315(a)(17) (Patient-specific education resources), or both. While these capabilities are more functional than exchange-oriented, they could complement and enhance the two certification criteria we have proposed to be part of the Patient Engagement Package.

We clarify that if an EHR Module were certified to the certification criteria included in a certification package definition, then the EHR Module developer would be able to indicate this fact without the need for any additional determination to be made by the ONC–ACB. In other words, ONC–ACBs would not have to perform any additional analysis or make any additional determination before an EHR Module developer could indicate that its certified EHR Module meets a certification package definition. However, to ensure that certification packages are represented accurately to potential purchasers and users of EHR Modules, we propose to modify § 170.523(k)(1) to require ONC–ACBs to ensure that an EHR Module developer accurately represents the certification packages its EHR Module meets if and when the EHR Module developer uses the certification package designation(s) on its Web site and in marketing materials, communications statements, or other assertions related to the EHR Module's certification. Although ONC–ACBs are already required to ensure that the certifications issued to EHR Modules (which would indicate the criteria to which the EHR Module is certified) are accurately represented by EHR Module developers, this proposed provision would expressly impose the requirement with regard to certification packages.

We also clarify that the certification criteria included in a certification package would be a minimum threshold, meaning that an EHR Module could be certified to other certification criteria adopted by the Secretary in subpart C of part 170 in addition to the certification criteria included in the certification package at issue. Thus, in the event that an EHR Module presented for certification satisfies the certification criteria included in each of the proposed certification packages and is also certified to other certification criteria, it could be so indicated by the EHR Module developer to its customers. For example, it could be certified as a non-MU EHR Module with care coordination and patient engagement packages.

Again, we believe this certification package approach could simplify communication between EHR Module developers and purchasers as well as make EHR Modules that meet a certification package definition easier to identify on the CHPL. We intend to indicate on the CHPL the certification packages an EHR Module satisfies based on whether the certification criteria to which the EHR Module is certified satisfy one or more certification package definitions. We believe this simplification may be especially valuable to health care providers that are ineligible to receive incentive payments under the EHR Incentive Programs because the EHR Module developers that serve them may only seek EHR Module certification to certification criteria included in a package.

V. Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking

In this section, we specifically request comment on issues we are considering addressing in the rulemaking in which we would propose to adopt the 2017 Edition certification criteria.

A. Additional Patient Data Collection

We are considering whether we should require the collection and use of certain patient generated data in the 2017 Edition. We believe there are valid reasons and evidence, as discussed below, for certification to ensure that EHR technology is capable of recording data beyond those currently required for MU. However, we believe it best to present these data and rationale for public consideration and comment before including them in any proposed 2017 Edition certification criteria. For the data discussed below, we anticipate that they would be proposed in a 2017 Edition rulemaking as part of a new or existing certification criterion that would require EHR technology to:

• Enable a user to electronically record, change, and access the [data]; and

• Record a patient's response as ''declined to provide.''

The functionality under consideration to record the data discussed below has no bearing on whether a patient chooses to provide this information or whether a health care provider chooses to record the information or would be required to do so through the EHR Incentive Programs or other programs. Further, while the certification criterion or criteria that we are considering for these data would not require to EHR technology to have the capability to electronically transmit the information, we welcome comments on whether we should also consider that capability as well.

In considering the appropriateness of the data elements and standards below, please comment on whether these data elements should be include in:

• A 2017 Edition ''demographics'' certification criterion (i.e., in a criterion with the functionality to enable a user to electronically record, change, and access patient data on preferred

language, sex, race, ethnicity, and date of birth);

• New standalone certification criteria for each data element; and/or

• New certification criteria together (e.g., disability, sexual orientation and gender identity in one certification criterion with veterans status and occupation status in a separate certification criterion).

Disability Information and Accommodation Requests

In discussions with the HHS Office for Civil Rights and HHS Administration for Community Living/ Center for Disability and Aging Policy, we have considered the potential benefits to patients and health care providers alike if EHR technology could enable a user to electronically record, change, and access information about a patient's disability status and any accommodate requests. For example, a patient may have limited sight or mobility and may need patient aids to interact with the provider or with the provider's EHR technology (e.g., a patient portal or secure messaging). We believe that health care providers could be better prepared to engage and treat patients with disabilities when they seek care if they were aware of the patient's disability status and any accommodate requests. Accordingly, we seek comment on whether certification should require that EHR technology be capable of enabling a user to electronically record, change, and access disability information *and/or* accommodation requests.

The following are a potential list of questions that could be asked related to disability information and accommodation requests. The questions (except for the Limited English Proficiency one) were adapted from questions that were approved by the Data Council and promulgated by the HHS Secretary under Section 4302 of the Affordable Care Act.[108] The questions align with the Census Bureau's American Community Survey [109] and are designed to characterize functional disability. The questions reflect how disability is conceptualized consistent with the International Classification of Functioning, Disability, and Health and serve as the minimum standard for collecting population survey data on disability status. As we mentioned in the 2014 Edition Final Rule, unlike clinical cognitive or functional status assessments, this information can be used by health care providers to better accommodate and respond to individual patient needs.[110]

1. Are you deaf or do you have difficulty hearing? If so, what special assistance may you need?

2. Are you blind or do you have difficulty seeing, even when wearing glasses? If so, what assistance may you need?

3. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? (patients 5 years old or older).[111] If so, what assistance may you need?

4. Do you have difficulty walking or climbing stairs? (patients 5 years old or older) If so, what assistance may you need?

5. Do you have difficulty dressing or bathing? (patients 5 years old or older). If so, what assistance may you need? [112]

6. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (patients 15 years old or older). If so, what assistance may you need?

7. Do you have difficulty communicating, reading, or do you have limited proficiency in English? If so, what assistance may you need?

We request comment on whether:

• These questions are the right questions to ask (with yes/no responses and a field for additional explanation);

• These questions and answers can be accurately and efficiently recorded in an EHR;

• There are alternative questions that could be asked related to disability status and additional assistance requests;

• There are other ways for capturing patients' needs in EHR technology and patients' needs related to interacting with EHR technology; and

• There are any available standards that could be used to capture in an EHR the listed questions (and answers) or *any* disability information and accommodation requests in a structured way. For example, would the following standards be appropriate for the associated information or suffice to code the listed questions and answers:

○ ICF (International Classification of Functioning, Disability and Health) for categories of function;

○ LOINC® for assessment instruments; and

○ SNOMED CT® for appropriate responses.

As we noted in the introduction to this section, while the certification criterion that we are considering for capturing disability status and accommodation requests would not require EHR technology to have the capability to electronically exchange the information, we welcome comments on the appropriateness of such functionality and whether the seven specified questions above or other recorded disability status and accommodation request information could be efficiently exchanged in structured data, if appropriate. We note that the 2014 Edition ''transition of care'' certification criteria and the proposed 2015 Edition ''transition of care'' certification criterion already include requirements for EHR technology to be capable of using the Consolidated CDA for exchanging patient data on cognitive and functional status.

Sexual Orientation and Gender Identity

In response to the 2014 Edition NPRM, we received comments requesting the inclusion of sexual orientation and gender identity as data EHR technology should be able to record as part of the ''demographics'' certification criterion. For the 2014 Edition EHR certification criterion, we declined to include these data elements as the data elements included in the certification criterion were limited to only those necessary to support the associated MU objective and measure. Since the 2014 Edition Final Rule was published, the IOM issued ''Collecting Sexual Orientation and Gender Identity Data in Electronic Health Records: Workshop Summary.'' [113] This summary illustrates the clinical relevance for collecting information on both sexual orientation and gender identity. Specifically, the collection of this information can help to address health disparities for Lesbian, Gay, Bisexual and Transgender (LGBT) patients, including access to care and the quality

[108] *http://minorityhealth.hhs.gov/templates/content.aspx?ID=9232#1.*

[109] *http://www.census.gov/people/disability/methodology/acs.html.*

[110] 77 FR 54256.

[111] The specified age designations mean that the questions that include these designations only apply to patients older that the specified age. The underlying assumption is that patients younger than the specified age would inherently have the difficulties inquired about. This is consistent with the American Community Survey methodology.

[112] For the purposes of this question, dressing and bathing are considered functionally similar (strength, range of motion, transferring and supporting abilities) as the question seeks to generally determine the patient's functional ability and not attribute a ''yes'' to either ability or to be used for research purposes. This question will allow individuals recovering from long illnesses, paralysis, or post-surgery limitations to choose ''yes,'' and then identify issues they may need assistance with.

[113] *http://www.iom.edu/Reports/2012/Collecting-Sexual-Orientation-and-Gender-Identity-Data-in-Electronic-Health-Records.aspx.*

of care. Conversely, concerns have been raised about the need to balance privacy and security with data flow needs. For example, there are some additional protections required for data collected in federally funded substance abuse treatment programs regarding who has access to such data, but there are not similar additional protections for sexual orientation and gender identity data. Therefore, we seek comment on whether certification should require that EHR technology be capable of enabling a user to electronically record, change, and access data on a patient's sexual orientation and gender identity. To facilitate the standard capturing of this data, we request comment on whether the following code sets could be used to capture this information in a structured format:

- SNOMED CT® for sexual orientation.[114]
- SNOMED CT® for gender identity.[115]

U.S. Military Service

In recent years, U.S. Military service members have been returning from service in Iraq and Afghanistan and other various combat duty stations. A portion of these service members are returning with traumatic brain injuries, major limb injuries, and diagnoses of post-traumatic stress disorder as reported by the Department of Defense and Department of Veterans Affairs. Overall, the Veterans Health Administration (Department of Veterans Affairs) provides medical care to over 8.76 million veterans each year.[116] Because the Department of Veterans Affairs has eligibility requirements to be considered eligible for veterans' benefits and that process takes into consideration a variety of factors, we do not seek comment on EHR technology's ability to record ''veteran status.'' However, we do seek comment on whether EHR technology should be capable of recording whether a patient has served in the U.S. Military. We believe recording U.S. Military service information can have many benefits. It can help in identifying epidemiological risks for patients such as those noted above. It can assist in ensuring that a patient receives all the health care benefits he or she is entitled to by alerting medical professionals to the patient's U.S. Military service history, which can facilitate the coordination of benefits. This information can also increase the ability to assemble a longitudinal record of care for a U.S. service member, such as by requesting or merging of a patient's electronic health record stored by the Department of Defense, Veteran's Health Administration, and/or another health care provider. Accordingly, we seek comment on whether certification should require that EHR technology be capable of enabling a user to electronically record, change, and access U.S. Military service information. We also seek comment on whether the ''U.S. Military service'' data element should be expanded to encompass all uniformed service members, including commissioned officers of the U.S. Public Health Service and the National Oceanographic and Atmospheric Administration as they too are eligible for veterans benefits and related services.

In terms of electronically capturing U.S. Military service, we request comment on the following:

- Use of the following concepts for coding U.S. Military service in EHR technology: History of Employment in U.S. Military; No History of Employment in U.S. Military; and Currently Employed by U.S. Military.
- Whether it would be appropriate to capture the actual start date and date of separation from service.
- Whether EHR technology should be able to record the foreign locales in which the service member had recently served.
- Whether there are better concepts/values that could capture information related to U.S. Military status or uniformed service status, including through capturing occupational status and use of occupational code sets.

As we noted in the introduction to this section, while the certification criterion that we are considering for capturing U.S. Military service would not require EHR technology to have the capability to electronically exchange the information, we welcome comments on the appropriateness of such functionality. We understand that the Consolidated CDA Social History Observation section could accommodate military or uniformed service status pending the assignment of specific codes (e.g., SNOMED CT), which would enable it to be exchanged as part of a summary care record. Therefore, we seek comment on the feasibility of capturing military or uniformed service status in the Consolidated CDA and whether the 2017 Edition should require EHR technology to be capable of exchanging this data (e.g., in the 2017 Edition ''transition of care'' certification criterion).

Work Information—Industry/Occupation

The Institute of Medicine has identified patients' work information as valuable data that could be recorded by EHR technology and used by both health care providers and public health agencies.[117] Similarly, the 2012 HHS Environmental Justice Strategy and Implementation Plan echoed the potential benefits of having work information in EHR technology.[118] The combination of current industry and occupation (I/O) information provides opportunities for health care providers to improve patient health outcomes—both for health issues wholly or partially caused by work and for health conditions whose management is affected by work. For example, ''Usual'' (longest-held) I/O information can be key for health care improvement and population-based health investigations, and is already a required data element for cancer reporting.[119] Health care providers can use also I/O information to assess symptoms in the context of work activities and environments, inform patients of risks, obtain information to assist in return-to-work determinations, and evaluate the health and informational needs of groups of patients.

The National Institute for Occupational Safety and Health (NIOSH) and other stakeholders are working to develop and support standards and tools for the collection, storage, and exchange of I/O information. It has developed a relational information model of work information (including I/O) for EHR technology and is in the process of translating it into the HL7 reference information model format. NIOSH is also working with HL7 to reflect functionality for work information in

[114] Codes of: Asexual; bisexual; gay; heterosexual; lesbian; questioning (a person who is questioning his or her sexual orientation); decline to answer; and not applicable (ages 0–17).

[115] Codes of: Gender variant; man; intersex; questioning (a person who is questioning his or her sexual orientation); transgender; woman; decline to answer; and not applicable (ages 0–17). These codes were recommended for creation by HL7, but not have yet been updated within SNOMED CT®.

[116] *http://www.va.gov/health/*.

[117] IOM (Institute of Medicine). 2011. ''Incorporating Occupational Information in Electronic Health Records: A Letter Report''. Available at: *http://www.nap.edu/catalog.php?record_id=13207*.

[118] U.S. Department of Health and Human Services. February, 2012. 2012 HHS Environmental Justice Strategy and Implementation Plan. Available at: *http://www.hhs.gov/environmentaljustice/strategy.html*.

[119] CDC (2) (Centers for Disease Control and Prevention). 2012. Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA) Release 1.0, August 2012. Available at: *http://www.cdc.gov/phin/library/guides/Implementation_Guide_for_Ambulatory_Healthcare_Provider_Reporting_to_Central_Cancer_Registries_August_2012.pdf*.

EHR technology and is collaborating with other stakeholders to ensure that I/O information is incorporated into interoperability standards, such as standards to support case reporting to public health. A reusable CDA template of Occupational Data for Health (ODH) is part of the social history section within the published Healthy Weight (HW) trial implementation profile,[120] which has been tested at the 2014 Integrating the Healthcare Enterprise Connectathon.[121] In addition, prototype occupation-related CDS knowledge bases for primary care providers are in development.

Widely used code sets are available for converting narrative I/O text into structured data. The combination of Bureau of Census (BOC) I/O codes [122] and NIOSH-added codes (e.g., for unpaid workers)—identified as the CDC_Census system in the Public Health Information Network Vocabulary Assignment and Distribution System (PHIN VADS) [123]—can be used to code patient I/O in EHR technology. The CDC_Census code sets are already used to classify the I/O information provided by respondents in most major U.S. health surveys. Given all of the effort by NIOSH and other stakeholders to advance this important work, we request comments on whether we should propose as part of the 2017 Edition that EHR technology be capable of enabling a user to electronically record, change, and access the following data elements for certification:

- Narrative text for both current and usual industry and occupation (I/O), with industry and occupation for each position linked and retained in perpetuity and time stamped.
- CDC_Census codes for both current and usual I/O, with industry and occupation for each position linked and retained in perpetuity and time stamped.

We solicit public comment on the experience EHR technology developers, EPs, EHs, and CAHs have had in capturing, coding, and using I/O data. Further, as cited under the U.S. Military service discussion above, I/O codes may be appropriate for coding U.S. Military service or uniformed service, as both data elements capture information on positions held/work performed and exposures. The Department of Veterans Affairs and HHS are currently assessing how best to appropriately and efficiently capture I/O information and military service information about patients in EHR technology. We welcome comments and suggestions on any potential options we should consider for our assessment.

B. Medication Allergy Coding

General allergy types can be coded using the RxNorm vocabulary that we have adopted in our rules. However, for coding medication allergies, RxNorm is not specific enough to distinguish allergies to particular ingredients in drugs nor is it specific enough for coding food-drug allergies. Allergic reaction symptoms and DDI reactions can be coded using the SNOMED CT vocabulary also adopted in our rules, but there is no specific reaction value set and using general problem value sets do not allow for identification of the allergy's cause. No formal reaction list has been defined in the C–CDA or through the work done by the Health Information Technology Standards Panel.[124] In the HITPC's meaningful use Stage 3 Request for Comment, stakeholders commented that other vocabulary and value sets could be leveraged to address these gaps. These include:

- The FDA Unique Ingredient Identifier (UNII) system which can be used to identify unique ingredients in drugs, biologics, food, and devices;
- The VA National Drug File—Reference Terminology (NDF–RT) vocabulary which has been mapped to RxNorm and may be a good standard for describing allergies to classes of drugs such as penicillin.

Additionally, CDC has developed a value set for Vaccine Reaction and Adverse Events [125] that is available but not currently assigned to drug and general allergic reactions.

The HITPC has indicated [126] that EHR systems should provide functionality to code medication allergies, including the related drug family for reactions. Currently, we require that CEHRT base CDS interventions on certain data (including medication allergies) but this list does not specifically include DDI reactions. Given these issues, we solicit comment on:

(1) The adoption of additional vocabularies to code medication allergies to drug ingredients, allergic reaction symptoms, and DDI reactions (e.g., UNII, NDF–RT);

(2) Whether we should adopt the CDC Vaccine Reaction and Adverse Event value set;

(3) The value of using specific reaction value sets versus general problem value sets;

(4) Whether CDS interventions should be based on DDI reactions.

C. Certification Policy for EHR Modules and Privacy and Security Certification Criteria

In our past rulemakings we have discussed and instituted two different policy approaches for ensuring that EHR Modules meet privacy and security (P&S) certification criteria while minimizing the level of regulatory burden imposed on EHR technology developers. In the 2011 Edition, we required that EHR Modules must meet all P&S certification criteria unless the presenter could demonstrate that certain P&S capabilities were either technically infeasible or inapplicable. In the 2014 Edition, we eliminated the requirement for each EHR Module to be certified against the P&S criteria. Rather, the P&S criteria were made part of the ''Base EHR definition'' that all EPs, EHs, and CAHs must have EHR technology certified to meet, in order to ultimately have EHR technology that satisfied the CEHRT definition. While some commenters expressed concern with our 2014 Edition proposal to remove the P&S certification requirement for EHR Modules, we finalized the policy in favor of the outcome-oriented requirement we believed the Base EHR definition promoted, and in an effort to enable EHR technology developers to better choose which P&S criteria were most applicable to their products. As of December 31, 2013, approximately 70% of 2014 Edition EHR Modules have been certified to at least one P&S criterion (out of nine available P&S criteria) and about 51% have been certified to four or more. Despite prior stakeholder concerns, this data suggests that our 2014 Edition Final Rule policy has not resulted in a significant reduction in the number of EHR Modules certified to P&S criteria and that a majority of EHR technology developers appear to be pursuing certification to these criteria regardless of our more flexible, less burdensome policy for 2014 Edition certification.

On March 23, 2013, the HITSC recommended that we should change our EHR Module certification policy for P&S. They recommended that each EHR Module presented for certification should be certified through one or more of the following three paths:

[120] *http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_HW.pdf.*

[121] *http://www.ihe.net/Connectathon/.*

[122] Census (1) (United States Census Bureau). 2012. Industry and Occupation. Available at: *http://www.census.gov/people/io/methodology/indexes.html.*

[123] PHIN Vocabulary Access and Distribution System. 2012. Available at: *http://www.cdc.gov/phin/tools/PHINvads/.*

[124] *http://www.hitsp.org/.*

[125] *http://phinvads.cdc.gov/vads/ViewValueSet.action?id=635A4FEA-8232-E211-8ECF-001A4BE7FA90.*

[126] *http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf.*

• Demonstrate, through system documentation and certification testing, that the EHR Module includes functionality that meets at least the ''minimal set'' [127] of privacy and security certification criterion.

• Demonstrate, through system documentation sufficiently detailed to enable integration, that the EHR Module has implemented service interfaces that enable it to access external services necessary to conform to the ''minimal set'' of privacy and security certification criterion.

• Demonstrate through documentation that the privacy and security certification criterion (and the minimal set that the HITSC defined) is inapplicable or would be technically infeasible for the EHR Module to meet. In support of this path, the HITSC recommended that ONC develop guidance on the documentation required to justify inapplicability or infeasibility.

As a result of the HITSC recommendations and stakeholder feedback, we seek comment on the following four options we believe could be applied to EHR Module certification for privacy and security:

• *Option 1:* Re-Adopt the 2011 Edition approach.

• *Option 2:* Maintain the 2014 Edition approach.

• *Option 3:* Adopt the HITSC recommendation. This approach reintroduces some of the challenges we sought to avoid with our current policy and introduces potentially new administrative burdens for EHR technology developers.

• *Option 4:* Adopt a limited applicability approach—under this approach, ONC would establish a limited set of P&S functionality that every EHR Module would be required to address in order to be certified. For example, we could require that all EHR Modules need to address the authentication, access control, and authorization certification criterion. This approach has the same downsides as options 1 and 3 but to a lesser extent given that its broad applicability could still result in EPs, EHs, and CAHs adopting EHR Modules that had been certified with duplicative capabilities.

We seek feedback on all of these policy options. Further we especially solicit feedback: (1) from EHR technology developers and ONC–ACBs regarding the efficiency of the current certification policy; (2) from stakeholders that prefer ''option 3'' (the HITSC's recommendation) and why; and (3) from stakeholders that prefer ''option 4'' what the minimum P&S criteria could be.

D. Provider Directories

We have received feedback from many different stakeholder groups that a single standard for ''provider directories'' is needed. The impetus for this feedback appears to be MU Stage 2's added exchange requirements and a general industry need to find providers electronic service information. In June 2011, The HITPC recommended [128] that we consider the adoption of provider directory capabilities in our certification program as well as work to address many of the issues they raised. To address the HITPC's recommendations, ONC launched a number of initiatives to define a single provider directory standard and to pilot its use. In August 2013, the HITPC recommended including a provider directory standard in MU Stage 3.[129]

After multiple discussions and guidance with subject matter experts in the field, we found that the main gap that stakeholders would like ONC to address through EHR certification is the ability to be able to query individual directory sources and directory sources federated by third parties such as HIOs, RHIOs, HISPs etc. This is also known as ''federated querying.'' However, we also discovered that there were only a few implementations of federated querying across the country and many were unique due to the lack of a single standard. Given this challenge, and its potential to inhibit exchange, ONC launched an open source project called ''Modular Specification Provider Directories (MSPD).'' [130]

During this project stakeholders collaborated to identify requirements for the next version of ''Healthcare Provider Directory (HPD)'' in order to provide a unified vendor-neutral platform for implementation of provider directories that supports both federated and non-federated architectures. The project resulted in implementable, testable specifications, and high quality test cases that verify conformance to the ''test implementation'' which is created based on the MSPD IG. In addition, ONC awarded a grant to the EHR | HIE Interoperability Workgroup [131] to pilot provider directory standards with multiple states.

It is our understanding that the current HPD standard created by Integrating the Healthcare Enterprise (IHE) [132] only addresses transactions between the client and a single provider directory with a single data source. While the standard can be used for federation, it does not address the complexities introduced by federation; provide a well-defined and straightforward approach to error handling, support targeted queries to federated data sources, or define mechanisms by which to distinguish the source of results in a given response. ONC is currently working with IHE and other stakeholders to solve these issues with an updated HPD standard.

In collaboration with IHE we believe that a new HPD standard will be ready in early 2014 that will support federated querying of provider directories. As a result, we believe that the updated HPD standard will be ready to propose for adoption as part of the 2017 Edition rulemaking and included in a certification criterion focused on capabilities to query provider directories. Accordingly, we seek public comment on the following potential capabilities we are considering for such a certification criterion:

At a minimum, EHR technology would need to be able to query provider directories for the following information and electronically process the response returned in accordance with the MSPD IG requirements (which are expected to be adopted by IHE USA as an IHE USA profile):

• Query for an individual provider;

• Query for an organizational provider;

• Query for relationships between individual providers and organizational providers.

E. Oral Liquid Medication Dosing

Our strategic goal is to provide more granular descriptions of prescriptions to allow for CDS, identify patient safety issues (such as excessive acetaminophen in combination medications), and reduce dosing confusion. For example, the U.S. currently uses the English measurement system standard (e.g., teaspoons) rather than the metric standard (e.g., milliliters (mL)) for prescribing liquid oral medications. The medication dose is

[127] The minimal set includes Authentication, access control, and authorization, Auditable events and tamper resistance, Audit report(s), Amendments, Automatic log-off, Emergency access, End-user device encryption, and Integrity. The full recommendation can be found at: *http://www.healthit.gov/sites/default/files/pswg transmittalmemo_032613.pdf.*

[128] *http://www.healthit.gov/sites/default/files/pdf/HITPC_transmit_InfoExchWG_May2011-finalsigned.pdf.*

[129] *http://www.healthit.gov/FACAS/sites/faca/files/IE%20WG_Recommendation%20Transmittal_MU3v2.docx.*

[130] *http://modularspecs.siframework.org/Provider+Directories+Homepage.*

[131] *http://www.interopwg.org/*

[132] *http://wiki.ihe.net/index.php?title=Healthcare_Provider_Directory.*

determined in part by the patient's weight. The metric standard (mL) offers more precision in medication dose, which can decrease preventable adverse drug events. Dosing errors are the most common medication error in pediatrics.[133] The American Academy of Pediatrics (AAP) supports the use of the metric standard (mL) for e-prescribing.[134] AAP supports modification of both dosing guidelines and dose-screening parameters to support dosing for every indication that warrants modified dosing regimens.[135] The Food and Drug Administration has provided a draft guidance that supports metric units for labeling prescription medications.[136] And, the National Council for Prescription Drug Programs supports mL dosing in retail dispensing.[137]

We understand that e-prescribing functionality can present standard dosing formula to use the patient's weight to: Calculate a dose; convert the dose to a volume for liquids; and present the dose in a format that is least likely to be confusing to a prescriber, pharmacist, nurse, or patient. Sophisticated e-prescribing functionality has been said to use individual dose limits, compared to weight- or body surface area-based normal values.

Given the clinical need and stakeholder support for reducing preventable adverse events resulting from dosing errors in e-prescribing, we solicit comment on whether we should adopt a certification criterion (or establish a requirement within a certification criterion) for EHR technology to use the metric standard for prescribing oral liquid medications or to solve the problem more generally using a structured Sig[138] standard. Potential (non-mutually exclusive) options for certification include, but are not limited to:

- Require EHR technology to use a structure Sig with explicit dosing units, frequency, and number of units;
- Require EHR technology to provide the metric standard as one option to record liquid medication doses;
- Require EHR technology to record liquid medication doses in the metric standard only; and
- Require EHR technology to be able to accurately convert a liquid dose to the metric standard. For this last option, we are also soliciting comment on minimum/maximum dosing checks for dose conversion.

We also solicit comment on EHR readiness to implement the metric standard for prescribing oral liquid medications, the effect on existing vocabulary standards for units of measurement (e.g., UCUM), and implications on the structured Sig format for e-prescribing.

F. Medication History

Knowing a patient's medication history can assist providers in making decisions about a patient's health, reduce the amount of time spent on administrative tasks around medication prescribing and reconciliation, improve patient safety, and quality of care in all health care settings. We are aware of current technology that provides medication history information through e-prescribing and EHR systems from community pharmacies and patient medication claims history. Current medication history services provide information such as patient compliance with prescribed medications, therapeutic interventions, drug-drug and drug-allergy interactions, adverse drug reactions, duplicative therapy, the numbers of pharmacies and physicians, and frequency of prescription refills. In a few cases, medication history services are provided through state and regional health information exchanges.

In the 2014 Edition, we adopted the NCPDP SCRIPT 10.6 standard for e-prescribing (170.314(b)(3)). SCRIPT 10.6 supports a medication history source feature that provides where the history was obtained and the identity of the source, as well as consolidates histories from different sources.

We solicit comments on whether we should propose a 2017 Edition certification criterion focused on medication history capabilities. We encourage commenters to address the specific information/specific capabilities that should be provided, standards recommended to support this capability, and which existing certification criterion/criteria could include this capability (e.g., medication reconciliation, medication list, e-prescribing) if it were not a stand-alone certification criterion.

G. Blue Button +

We are interested in feedback on the adoption of separate certification criteria for Blue Button + (BB+) capabilities as part of our 2017 Edition rulemaking. Blue Button+ is the ability to get patient records in a human-readable and machine-readable format, and allows the patient send them where they choose. This enables a consumer to do everything from printing a physical copy to sharing it with a third party application. Since the publication of the 2014 Edition Final Rule both members of the public and the HITSC have expressed interest in promoting Blue Button +. Specifically, stakeholders have indicated an interest in using the BB+ Direct Specifications, currently in pilot phase of the S&I Framework's BB+ Representational State Transfer (REST) workgroup,[139] and the BB+ RESTful API. The BB+ Direct Specifications add two functions beyond the MU Stage 2 requirements: the ability to use triggers to automate a ''Direct message'' to the patient after each encounter or when new clinical information is added to the record; and the ability to load certificate bundles, including the Blue Button certificate bundle. The BB+ REST specifications do not change content specifications, but include substantial changes to authentication and authorization using OAuth and OpenID, and Transport using FHIR instead of the Direct Protocol. Given stakeholder interest in the BB+ initiative's work and the significant benefits it could have for patients, we solicit comments on the following:

(1) Is there a market need for BB+ certification? In other words, would health IT developers find value in a BB+ certification that would enable them to say they are ''BB+ compliant'' or ''BB+ ready'';

(2) Which elements of BB+ Direct Specifications would be most important

[133] Wong IC, Ghaleb MA, Franklin BD, Barber N. Incidence and nature of dosing errors in pediatric medications: A systematic review. Drug Saf. 2004;27(9):661–670.

[134] AAP Council on Clinical Information Technology Executive Committee, 2011–2012. Policy Statement—Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management. Pediatrics 2013; 131;824.

[135] Johnson KB, Lehmann CU, and the AAP Council on Clinical Information Technology. Technical Report—Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management. Pediatrics 2013;131;e1350.

[136] FDA Draft Guidance for Industry on Safety Considerations for Container Labels and Carton Labeling Design To Minimize Medication Errors. April 24, 2013. *https://www.federalregister.gov/articles/2013/04/24/2013-09640/draft-guidance-for-industry-on-safety-considerations-for-container-labels-and-carton-labeling-design.*

[137] *https://www.ncpdp.org/Educational-Summit-Session.aspx?ID=6.*

[138] A prescription contains a number of different elements. In addition to the patient and prescriber information, it must state the name, dosage form and strength of the medication; the dose; the amount to be dispensed; the number of refills; and the directions for use, or Sig. ''Sig'' is an abbreviation for ''signatura,'' Latin for ''Mark thou''. The Sig contains the instructions explaining how the patient is to take the medication. *http://www.ncpdp.org/pdf/Sig_standard_imp_guide_2006–06.pdf.*

[139] More information on the S&I Framework's BB+ REST workgroup can be found at *http://wiki.siframework.org/BlueButton+Plus+Pilots.*

to reference in a certification criterion and how would they be tested; and

(3) What elements of BB+ REST Specifications would be most important to reference in a certification criterion and how would they be tested? Additionally, what use cases would be uniquely supported by BB + REST Specifications?

H. 2D Barcoding

Using barcode symbols on items with specific details, including specifications of the dispensed unit, has the potential to reduce medication and transcription errors.[140] In 2004, the FDA issued the ''Bar Code Label Requirements for Human Drug Products and Biological Products Final Rule'' [141] for the barcoding of pharmaceutical and biological products. The regulation required the National Drug Code (NDC) to be barcoded on certain pharmaceutical and biological items used in health care facilities using a linear barcode.

Implementation of two-dimensional (2D) barcodes on drug products and biologics such as vaccines can allow for rapid, accurate, and automatic capture of data by a handheld imaging device or scanner to populate fields in an EHR or specialty registry. 2D barcodes can contain more information than linear barcodes in a smaller space.[142] We are aware that 2D barcodes using the GS1 DataMatrix Barcodes standard are being introduced for unique device identifiers and vaccines.

For example, 2D barcode technology has been pilot tested to show that barcoding on vaccines can capture vaccine data elements completely and accurately.[143] The National Childhood Vaccine Injury Act [144] (NCVIA) requires documentation of vaccine product identification and vaccine lot number. These data are usually handwritten or manually typed into an EHR/IIS and can be missing or incorrect. A workgroup from the American Academy of Pediatrics (AAP) approached the FDA in 2010 to request that the regulation requiring linear barcodes be amended to allow for the use of 2D barcodes on vaccines.

Since 2011, the CDC has been exploring the potential for 2D barcoding to streamline immunization practices. Two vaccine manufacturers, ten CDC ''Section 317'' Immunization grantees, and approximately 220 immunizers among the ten grantees participated in a pilot implementation of 2D barcoded vaccines. Providers administered vaccines with 2D barcodes containing product identifier, lot number, and expiration date. The providers were given barcode scanners that read the 2D barcode and input the data directly into the EHR for each patient. The data were then sent to the IIS. Additionally, we are aware that a working group led by the AAP has developed a ''Guideline for Practitioners'' document to help practices use 2D barcoding with their EHR or IIS and guidance for manufacturers on implementing GS1 DataMatrix Barcodes standard on vaccines.[145]

Given the progress made to-date demonstrating the feasibility of implementing 2D barcode technology in practice, we solicit comment on whether we should propose a 2017 Edition certification criterion requiring EHR systems to consume 2D barcodes and for what functions (e.g., vaccine administration, medication administration). We also solicit comment on any other data that EHR technology could be required to capture using 2D barcoding information.

I. Duplicate Patient Records

In September 2013, in response to the 2011 HITPC and HITSC recommendations and stakeholder feedback, ONC formally undertook an initiative to improve patient matching.[146] Due to our experience with this initiative, we are considering a 2017 Edition certification criterion that would require EHR technology to be capable of generating and providing to end users reports that detail potential duplicate patient records as a potential means to improve patient matching data quality. We anticipate that this certification criterion could also include functionality for end users to correct duplicate records, which typically requires the merging of records and unmerging incorrectly merged records.

We believe a certification criterion including these capabilities, in addition to the patient matching capabilities proposed for inclusion in the 2015 Edition ''transitions of care'' certification criterion, would significantly improve a provider's ability to properly match patients to their health information. While many EHR systems today with built-in matching functionality and processes offer reports that identify potential duplicate records, not all EHR systems offer such a capability. Additionally, some EHR systems have the capability, but do not make the reports accessible to users. As for merging and unmerging, we understand these capabilities vary and are inconsistently applied in EHR technology today. While some EHR technology may enable users to merge and unmerge back to a specific point in time, others do not unmerge and instead delete the entire record and create two new ones.

We seek comment on provider demand for/interest in these types of capabilities in addition to any capabilities that should be included or excluded from this potential certification criterion.

J. Disaster Preparedness

Over the past decade, the U.S. has been challenged by several natural and man-made disasters (e.g., terrorist attacks, Hurricanes Katrina and Sandy, Joplin tornado) which have placed considerable strain on local health care systems and put health system readiness for public health emergencies on the national agenda. One of the basic tenets of preparedness is, to the greatest extent possible, to incorporate into everyday operations those systems, processes, equipment, and strategies that might be employed during a disaster.[147] Maintaining health IT infrastructure has tangible day to day benefits and during a disaster or other large scale event may reduce overall stress on the health care system which helps makes our health care systems more resilient. In fact, the National Health Security Strategy (NHSS) identifies ''the use of portable, standards-based, interoperable EHRs'' as an essential element of a ''prepared and responsive health system.'' [148]

For example, EHRs improved health care during a crisis on May 22, 2011 when a tornado struck Joplin, Missouri. As part of the devastation, St. John's Regional Medical Center was heavily damaged and had to be evacuated. All paper and film records were destroyed, but medical personnel had full access to their patients' electronic records. The EHR system significantly aided St.

[140] *http://www2.aap.org/immunization/pediatricians/pdf/barcoding_guidance_manufacturers_022212.pdf.*

[141] *http://www.fda.gov/ohrms/dockets/98fr/04-4249.htm.*

[142] *http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/about.html.*

[143] *http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/about.html.*

[144] Public Law 99–660.

[145] AAP materials are available at *http://www2.aap.org/immunization/pediatricians/barcoding.html.*

[146] *http://www.healthit.gov/buzz-blog/health-innovation/onc-launches-patient-matching-initiative/.*

[147] Abir M, Mostashari F, Atwal P, et al. Electronic health records critical in the aftermath of disasters. *Prehosp Disaster Med.* 2012;6:620–622.

[148] U.S. Department of Health and Human Services. National health security strategy of the United States of America. Washington, DC: U.S. Department of Health and Human Services; December 2009: *http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf* Accessed August 9, 2013.

John's in tracking patient medical histories and delivering care based on the full patient records even from their temporary facility.[149]

To more fully consider how EHR technology can be used to enhance emergency preparedness and assist in response when emergencies do occur, we seek comment (in collaboration with our colleagues in the Office of the Assistant Secretary for Preparedness and Response (ASPR)) on a number of different concepts that we believe could be expressed as certification criteria in the future.

In November 2012, ONC convened the Southeast Regional HIT–HIE Collaboration (SERCH) project on Health Information Exchange in Disaster Preparedness and Response.)[150] The consortium included representatives from Alabama, Arkansas, Florida, Georgia, Louisiana, and Texas. The consortium's goal was to develop a strategic plan for sharing health information data among the Southeast and Gulf states during and following a declared natural disaster. The consortium members carefully assessed the challenges of accessing medical records and coordinating health care information for patient populations displaced due to a disaster. The SERCH team recognized the importance of using existing EHR and HIE standards and concluded that ''current and future work [regarding electronic health information exchange during disasters] should leverage the standards being developed'' and that ''rather than focus on specifying a minimum data set, allow data set sources to contribute as much of the data within the proposed data set as they are able.''

One of the key issues encountered during disasters (and day-to-day emergency care) is how to bypass the naming of patients who are temporarily unidentified. While this is rarely an issue in other care settings, disasters and emergencies create situations in which care must begin before the identity of the patient can be verified. It is our understanding that most EHR technologies used in emergency care settings have a name bypass function or facilities have developed protocols to be employed in these cases. Unfortunately, stakeholder feedback from the field has indicated that there is little consistency with respect to the patient naming approach used in EHR technology during emergencies/disasters or how rapidly a set of patient records can be generated in a mass casualty situation. This makes reconciliation across various platforms or throughout the episode of care challenging. As a result, information is lost, care is disconnected, patient safety is threatened, and tests and procedures are often duplicated.

During facility evacuation it is often necessary to rapidly produce hard copies of patient records for groups of patients (for example all patients in the ''SICU'' or ''on floor 5 west''). This step is needed to ensure the continuity of care for patients en route and at the receiving facility, which may not have access to the patient's complete electronic record. It is our understanding that many EHR technologies today only permit clinical summaries for patients to be printed one at a time, which is too time consuming in situations where seconds count.

The nature of emergency and disaster care is that transitions of care and referrals happen at far greater speed and frequency than in other primary or ambulatory settings. The unique needs of tracking a patient through the episode of care, which may involve numerous, unaffiliated care providers (for example, shelters and triage stations, emergency medical services, initial emergency department, air medical transfer, tertiary center emergency department, specialty care, etc.) presents unique challenges. To improve the continuity of care during these rapid transitions, stakeholders have suggested that it would be helpful if a standardize set of core information can be rapidly transferred electronically across different EHR technologies. Numerous third-party patient tracking methods and software packages have emerged as add-ons to EHR technologies to help, but very few are part of the EHR technology and often create parallel tracking systems.

Disasters present a unique situation in which the demand for health resources (personnel, equipment, supplies, space, etc.) may temporarily exceed the supply. This situation requires a legal and ethical framework to fairly and equitably allocate these scarce resources to achieve the greatest possible population based outcomes. The IOM has published Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response,[151] in which the standards of care are altered based on the availability of health care resources. As such, it seems as if it would be particularly helpful if EHR technology were able to denote care provided during contingency and crisis conditions.

Improved public health surveillance has long been a promise of ubiquitous EHR technology. While great strides have been made, little attention has been focused on the potential of electronic heath data to evaluate resilience, preparedness, strain on the health care system, or recovery.

Given these issues, we solicit comments on:

(1) Whether there could be a standardized naming convention for EHR technology to use for temporarily naming unidentified patients during disaster and emergency events?

(2) Whether we should consider adopting a certification criterion that would be available for certification for EHR technology developers to show that their EHR technology can batch print face sheets or patient snapshots in bulk (by floor or unit, or by facility) to support movement/evacuation of large numbers of patients?

(3) Whether there are particular capabilities or standards we should consider as part of EHR certification that would better assist providers track and identify patients and victims and share basic clinical information quickly across the full continuum of care during everyday emergencies, disasters, and public health emergencies?

(4) Whether EHR technology should be able to denote care provided during disasters or public health emergencies and allow for designation of care provided under situations which demand contingency or crisis standards of care?

(5) Whether there are any EHR capabilities and certification criteria that we should consider for certification that could improve/expedite how EHR technology is used to report standardized and de-identified patient data to public health and emergency management authorities, in a manner that would allow such authorities the ability to measure, track and trend health system resiliency, stress, preparedness, and recovery?

K. Certification of Other Types of HIT and for Specific Types of Health Care Settings

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a voluntary certification program or programs for other types of HIT besides Complete EHRs and EHR Modules. As we noted in the Permanent Certification Program final rule (76 FR 1294), the *initial focus* of the ONC HIT Certification Program

[149] *http://www.healthit.gov/buzz-blog/ehr-case-studies/electronic-health-records-prove-invaluable-crisis/.*

[150] *http://www.healthit.gov/sites/default/files/pdf/SERCH-White-Paper.pdf.*

[151] IOM. 2012. Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response. Washington, DC: The National Academies Press.

should be on the certification of Complete EHRs and EHR Modules in support of the EHR Incentive Programs. In the 2014 Edition NPRM, we sought public comment on whether we should focus any certification efforts towards the HIT used by health care providers that are ineligible to receive incentive payments under the EHR Incentive Programs and received positive feedback that we discussed in the 2014 Edition Final Rule.[152] On March 7, 2013, in conjunction with CMS, we published the ''Advancing Interoperability and Health Information Exchange'' Request for Information (RFI) in the **Federal Register,** which stated that ONC and CMS would continue to collaborate on the EHR Incentive Programs and ONC HIT Certification Program to ensure that the programs support delivery and payment reform.[153] The RFI also noted that HHS intends to rely on all applicable and appropriate statutory authorities, regulations, policies, and programs to accelerate rapid adoption of health information exchange across the care continuum in support of delivery and payment reform. In response to comments received on the RFI, we issued a ''Principles and Strategy for Accelerating Health Information Exchange'' paper.[154] As summarized in the paper, commenters made multiple recommendations for the use of certification and the expansion of the ONC HIT Certification Program.[155] We stated in the paper: ''A critical part of enabling the secure flow of information across the system is advancing the adoption of HIT standards through voluntary certification of HIT and HIE products and services. CMS will consider various ways in which the voluntary certification of HIT and HIE products and services under the ONC HIT Certification Program could be aligned with Medicare and Medicaid payment policy, to the extent feasible and within the scope of applicable law.''

1. Other Types of HIT

This proposed rule takes a step towards the expansion of the ONC HIT Certification Program to accommodate other types of HIT. By proposing changes to the ONC HIT Certification Program to recognize the certification of MU and non-MU EHR Modules, EHR technology designed for other settings and purposes could be certified under the ONC HIT Certification Program to the 2015 Edition without having to meet certification criteria designed specifically for MU (see section IV.B for further discussion). This step, however, does not address the full range of HIT that might be certified to the certification criteria the Secretary may adopt in the future because all technologies would still be certified as ''EHR Modules'' even with our proposed changes. Visibility for stakeholders about the certifications issued and attribution for certifications that is more specific and distinct for other technologies that would not generally be considered ''EHR'' functionality, such as functionality provided by a health information exchange, HISP, or laboratory technology, would provide better marketing and purchasing clarity. With additional changes to the ONC HIT Certification Program, we could provide the proper visibility and attribution for these technologies by permitting them to be certified as ''HIT Modules.'' ''HIT Modules'' would be distinct from EHR Modules in that they would represent technologies that stakeholders recognize as distinct from EHR software and services. Certification for ''HIT Modules'' could also have long-term practicality as the ONC HIT Certification Program evolves. We welcome comments on this potential change to the ONC HIT Certification Program as we are considering moving in this direction as part of our 2017 Edition rulemaking.

2. Specific Types of Health Care Settings

To begin the processes noted in the ''Principles and Strategy for Accelerating Health Information Exchange (HIE)'' paper, we asked the HIT Policy Committee to begin exploring the expansion of certification under the ONC HIT Certification Program, particularly focusing on EHR certification for the long-term and post-acute care (LTPAC) and behavioral health care settings. We expect the Certification/Adoption Workgroup of the HIT Policy Committee to present final recommendations to the HIT Policy Committee and the HIT Standards Committee in March 2014. We have also received feedback and suggestions from other components of HHS about EHR technology certification for setting-specific and specialty purposes. EHR technology certification could potentially be expanded given stakeholder demand for specific certification criteria targeted to support specific purposes. Below are some examples on which we seek comment as well as any other suggestion the public may have.

- *Children's EHR Format*

The Children's EHR Format (''Format'')[156] was authorized by the 2009 Children's Health Insurance Program Reauthorization Act (CHIPRA)[157] and developed by the Agency for Healthcare Research and Quality (AHRQ) in close collaboration with CMS. The Format was developed to bridge the gap between the functionality present in most EHRs currently available and the functionality that would more optimally support the care of children. Specifically, the Format provides information to EHR system developers and others about critical functionality, data elements, and other requirements that need to be present in an EHR system to address health care needs specific to the care of children, especially those enrolled in Medicaid or the Children's Health Insurance Program (CHIP). Providers who care for children (e.g., pediatricians, family physicians, and specialists) have criticized the absence of these ''pediatric'' functions when they are not available in EHR technology. The availability of certification of EHR technology to the Format (or, more likely, key aspects of the Format) may stimulate EHR technology developers to recognize and incorporate pediatric functionality into EHR technology as well as further the goals of CHIPRA and the agencies responsible for implementing it.

- *Practice Transformation*

To fully support comprehensive primary and specialty care toward the aim of better care and better health outcomes at lower cost EHR technology may need to include more advanced and specific capabilities that are not uniformly or widely available today. For example, the ability of EHR technology to enable users to construct a customized risk stratification algorithm within EHR technology through selection of structured data elements (e.g., diagnosis, labs, medications, symptoms, risk factors, frequency of visits, hospitalization or ED visit). Alternatively, it could include the ability to modify or adapt standardized risk stratification algorithms that identify individual patients risk levels and clearly demarcate this risk level within a patient's record. Further, it has been suggested that EHR technology

[152] 77 FR 54275.

[153] 78 FR 14793.

[154] *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf.*

[155] For a summary of these recommendations, see page 5 of the ''Principles and Strategy for Accelerating Health Information Exchange (HIE)'' paper.

[156] *http://healthit.ahrq.gov/health-it-tools-and-resources/childrens-electronic-health-record-ehr-format.*

[157] Public Law 111–3, section 401.

should enable a user to modify risk stratification algorithms by adding more elements or applying a global risk assessment based on clinical judgment. In addition to risk stratification, EHR technology may need to be able to track patients for care management services based on risk status with the ability to create customizable real-time lists of patients in different tiers of risk.

As a second example in this category, we could adopt certification criteria for EHR technology that focuses on advanced care coordination features to integrate a patient's care plan into visit screens and other screens such that the patient view displays an updated and modifiable care plan documentation field. Further, a certification criterion could focus on ability to enable users to track tests and referrals that are in process and automatically trigger a reminder to view the results or follow up if results are not entered or received into the EHR by an expected date.

VI. Removal of the 2011 Edition EHR Certification Criteria and Related Standards, Terms, and Requirements and the Temporary Certification Program

A. 2011 Edition EHR Certification Criteria

We propose modifications to remove the 2011 Edition EHR Certification Criteria and related standards, terms, and requirements from the Code of Federal Regulations. Specifically, we propose to remove 45 CFR §§ 170.302, 170.304, and 170.306. We also propose to remove the standards and implementation specifications found in 45 CFR §§ 170.205, 170.207, 170.210, and 170.299 that are *only* referenced in the 2011 Edition EHR certification criteria. This means that if a standard is also referenced in the 2014 or 2015 Edition, it would remain in the regulation text. In regard to terms, we propose to retire the definitions found in 45 CFR § 170.102 related to the 2011 Edition, including ''2011 Edition EHR certification criteria'' and ''Complete EHR, 2011 Edition.'' In regard to requirements, we propose to remove § 170.550(e) and any other requirement in subpart E, §§ 170.500 through 170.599 that is specific to the 2011 Edition and does not have general applicability to other editions of certification criteria.

EHR technology certified to 2011 Edition is outmoded. It no longer meets the CEHRT definition and the 2011 Edition no longer represents an acceptable level of interoperability. Further, as referenced by the HHS Office of Inspector General and CMS in the recent rulemakings completed by those agencies around donations of EHR items and services, we expect to retire old/no longer applicable certification criteria editions.[158] This approach will streamline our requirements and ensure there is no regulatory confusion involving administration of ONC's rules and these other agencies' rules. Thus, consistent with EO 13563 instruction to ''determine whether any [agency] regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives,'' we are proposing to remove the 2011 Edition and related standards, terms, and requirements from the Code of Federal Regulations.

B. Temporary Certification Program

The temporary certification program sunset on October 4, 2012, and is no longer in existence (77 FR 54268). Accordingly, we propose to remove from the Code of Federal Regulations the associated regulations, consisting of subpart D (§§ 170.400 through 170.499).

VII. Response to Comments

Because of the large number of public comments normally received in response to **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document. As noted in section I.B.2, we do not plan to respond in that subsequent document to comments we receive concerning potential proposals for future rulemaking and the subject matter discussed in section V. ''Other Topics for Consideration for the 2017 Edition Certification Criteria Rulemaking.''

VIII. Collection of Information Requirements

This proposed rule contains no new collections of information under the Paperwork Reduction Act nor does it propose to revise current collections of information approved by OMB.

IX. Regulatory Impact Statement

A. Statement of Need

This proposed rule is being published to adopt a voluntary edition of certification criteria (2015 Edition). Certification criteria and associated standards and implementation specifications will be used to test and certify HIT in order to make it possible for EPs, EHs, and CAHs to adopt and implement HIT that can be used to meet the CEHRT definition. EPs, EHs, and CAHs who seek to qualify for incentive payments under the EHR Incentive Programs are required by statute to use CEHRT. The 2015 Edition provides an efficient and effective response to stakeholder feedback, incorporates ''bug fixes'' for errors, omissions and ambiguities found in our 2014 Edition EHR certification criteria, which will make our rules clearer and easier to implement, and includes newer standards and implementation specifications that reflect our commitment to promoting innovation and enhancing interoperability.

B. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

1. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this proposed rule is not an economically significant rule. Related costs to prepare EHR technology to be tested and certified are estimated to be less than $100 million per year. Nevertheless, because of the public interest in this proposed rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the proposed rule.

a. Costs

This rule proposes the adoption of standards, implementation specifications, and certification criteria

[158] CMS final rule ''Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements'' (78 FR 78751).

that would establish the capabilities that EHR technology would need to demonstrate to be certified to the 2015 Edition. Our analysis focuses on the direct effects of the provisions of this proposed rule—the costs incurred by EHR technology developers to develop and prepare EHR technology to be tested and certified in accordance with the certification criteria (and the standards and implementation specifications they include) adopted by the Secretary. That is, we focus on the technological development and preparation costs necessary for EHR technology already certified to the 2014 Edition EHR certification criteria to upgrade to the proposed 2015 Edition EHR certification criteria and for developing a new EHR Module to meet the 2015 Edition EHR certification criteria. The costs for testing and certification of EHR technologies to the 2015 Edition were captured in the regulatory impact analysis of the Permanent Certification Program final rule as we discuss in more detail below (IX.B.1.a.iii ''Testing and Certification Costs for the 2015 Edition''). The costs that EPs, EHs, and CAHs will incur in adopting and implementing EHR technology certified to the 2015 Edition are not within the scope of this final rule.

i. Development and Preparation Costs for the 2015 Edition

The development costs we estimate are categorized based on the type of certification criteria we have identified for the purposes of gap certification (i.e., new, revised, and unchanged). For the 2014 Edition Final Rule, we used the total number of unique Complete EHRs and EHR Modules that had been certified to the 2011 Edition EHR certification criteria as identified in the CHPL for our regulatory impact analysis. At this point in time, we do not believe the CHPL is fully populated with all of the EHR technologies that will be certified to 2014 Edition EHR certification criteria. Accordingly, we are using the total number of unique [159] 2011 Edition Complete EHRs and EHR Modules that were used for MU Stage 1 attestation as reported at the end of FY 2013.[160] We expect, however, that upon issuance of the 2015 Edition Final Rule that the CHPL would provide a more complete picture of the number of EHR technologies certified to the 2014 Edition for use in our regulatory impact analysis and that we would use those numbers instead of the 2011 Edition numbers we include here for our current estimates.

Using the unique number of 2011 Edition EHR technologies used for MU Stage 1 attestation we have established a range of EHR technologies that we believe will be developed and prepared to meet each of the proposed 2015 Edition EHR certification criteria based on the following four considerations:

- Before a subsequent 2015 Edition final rule is issued, many, if not most, EPs, EHs, and CAHs will have EHR technology certified to the 2014 Edition that can be used to meet the CEHRT definition for FY/CY 2014 and FY/CY 2015 because they must use EHR technology that has been certified to the 2014 Edition to meet the CEHRT definition beginning with FY/CY 2014.
- Unlike the 2014 Edition, the 2015 Edition is a voluntary edition of EHR certification criteria to which EPs, EHs, and CAHs *are not required* to possess EHR technology certified in order to meet the CEHRT definition on a certain date.
- The CEHRT definition only requires EPs, EHs, and CAHs to possess the CEHRT they need to demonstrate MU for the stage they seek to accomplish, which could conceivably directly affect the number of EHR technologies developed to certain certification criteria that support MU menu objectives and measures.
- Some EHR technology will be developed and prepared to meet the 2015 Edition that is not intended to be used by providers solely for MU purposes.
- Some EHR technology developers may wait to see what the 2017 Edition includes in a 2017 Edition proposed rule, potentially certify EHR technology to the 2015 Edition, and then pursue gap certification to the final 2017 Edition.

Based on these assumptions, we believe that between 20% and 40% of unique EHR technologies used for MU Stage 1 will be developed and prepared for certification to the 2015 Edition. This range takes into account potential new entrants to the market as well as those EHR technologies used for MU Stage 1 attestation that may no longer be brought forth for certification because of such factors as corporate re-organizations (e.g., mergers and acquisitions) as well as the loss of market share for some EHR technologies.[161] This range also takes into account any potential non-MU-focused EHR technologies that will be developed and prepared to meet the 2015 Edition, but not designed for MU purposes. For unchanged certification criteria, we have only calculated development and preparation costs for 25–50 new EHR technologies. There would not be any costs associated with upgrading EHR technologies previously certified to the 2014 Edition and we do not expect any more than 25–50 new technologies to be certified to the unchanged 2015 Edition EHR certification criteria.

We are not aware of an available independent study (e.g., a study capturing the efforts and costs to develop and prepare Complete EHRs and EHR Modules to meet the requirements of the 2014 Edition EHR certification criteria) that we could rely upon as a basis for estimating the efforts and costs required to develop and prepare EHR technology to meet the 2015 Edition EHR certification criteria. Therefore, we have relied upon the approach we used for estimating the costs associated with developing and preparing EHR technology to meet the 2014 Edition EHR certification criteria in the 2014 Edition NPRM and 2014 Edition Final Rule (i.e., we have used our own research to estimate the effort required to develop and prepare EHR technology to meet the requirements of the 2015 Edition.).[162] We have identified three levels of effort that we believe can be associated with the development and preparation of EHR technology to meet the requirements of the 2015 Edition. These levels of effort are the *average* range of hours we would expect to be necessary to develop EHR technology to meet the requirements of the 2015 Edition EHR certification criteria. This means that a few EHR technology developers' costs may be less than this range and a few may exceed the range. Level 1 is for certification criteria that we believe will require the least amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 40–100 hours. Level 2 is for certification criteria that we believe will require a moderate amount of effort to develop and prepare EHR

[159] We attempted to discern how many Complete EHRs and EHR Modules were used that would not constitute a newer version of the same EHR technology.

[160] For 2015 Edition EHR certification criteria that do not have equivalent 2011 Edition EHR certification criteria, we used the unique number for the equivalent 2014 Edition EHR certification criteria as identified and used for the 2014 Edition Final Rule regulatory impact analysis.

[161] This may be happening with EHR technologies being developed and prepared for certification to the 2014 Edition based on the number of certified EHR technologies listed on the CHPL as of October 2013.

[162] We have also estimated the costs for the proposed revisions to the 2014 Edition ''transmission to public health agencies—syndromic surveillance'' certification criterion (§ 170.314(f)(3)).

technology for testing and certification to the criteria, with a range of 100–300 hours. Level 3 is for certification criteria that we believe will require the most amount of effort to develop and prepare EHR technology for testing and certification to the criteria, with a range of 300–400 hours.

We have based the effort levels on the hours necessary for a software developer to develop and prepare the EHR technology for testing and certification. The U.S. Department of Labor, Bureau of Labor Statistics estimates that the mean hourly wage for a software developer is $44.85.[163] We have also calculated the costs of an employee's benefits by assuming that an employer expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. We have rounded up the average software developer's wage with benefits to $61 per hour.

To calculate our low cost estimates for each certification criterion in the tables below, we have multiplied the low number of the estimated range of EHR technologies expected to be developed and prepared by the low number of estimated hours for a software developer to develop and prepare the EHR technologies for testing and certification. To calculate our high cost estimates for each certification criterion in the tables below, we have multiplied the high number of the estimated range of EHR technologies expected to be developed and prepared to the criterion by the high number of estimated hours for a software developer to develop and prepare the EHR technologies for testing and certification. For the following tables (Tables 5 through Table 11), dollar amounts are expressed in 2014 dollars.

New Certification Criteria

TABLE 5—2015 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(h)(1)	Transmit—Applicability Statement for Secure Health Transport.	171–342	.42	2.09
170.315(h)(2)	Transmit—Applicability Statement for Secure Health Transport & XDR/XDM for Direct Messaging.	137–274	.33	1.67
170.315(h)(3)	Transmit—SOAP Transport and Security Specification & XDR/XDM for Direct Messaging.	137–274	.33	1.67
Total			1.08	5.43

TABLE 6—2015 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(a)(20)	Implantable device list	151–303	.93	5.54
170.315(h)(4)	Transmit—Applicability Statement for Secure Health Transport & Delivery Notification in Direct.	32–65	.20	1.19
Total			1.13	6.73

TABLE 7—2015 EDITION NEW EHR CERTIFICATION CRITERIA: LEVEL 3 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(c)(4)	Clinical quality measures—patient population filtering	152–303	2.78	7.39
170.314(g)(5)	Non-percentage-based measures reporting	151–303	2.76	7.39
Total			5.54	14.78

Revised Certification Criteria

[163] *http://www.bls.gov/oes/current/oes151132.htm.*

TABLE 8—2015 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 1 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(a)(5)	Demographics	202–403	.49	2.46
170.315(a)(11)	Electronic notes	93–187	.23	1.14
170.315(a)(17)	Patient-specific education resources	153–306	.37	1.87
170.315(b)(2)	Clinical information reconciliation and incorporation	158–317	.39	1.93
170.315(b)(4)	Incorporate laboratory tests and values/results	157–314	.38	1.92
170.315(b)(5)	Transmission of electronic laboratory tests and values/results to ambulatory providers (inpatient).	32–65	.08	.40
170.315(b)(6)	Data portability	149–298	.36	1.82
170.315(d)(2)	Auditable events and tamper-resistance	196–392	.48	2.39
170.315(e)(2)	Clinical summary (ambulatory)	132–264	.32	1.61
170.315(f)(2)	Transmission to immunization registries	145–289	.35	1.76
170.315(f)(4)	Transmission of reportable laboratory tests and values/results (inpatient setting).	26–51	.06	.31
170.315(f)(6)	Transmission to cancer registries	26–51	.06	.31
Total			3.57	17.92

TABLE 9—2014 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.314(f)(3)	Transmission to public health agencies—syndromic surveillance.	141–282	.86	5.16
Total			.86	5.16

TABLE 10—2015 EDITION REVISED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(a)(2)	CPOE—laboratory	189–378	1.15	6.92
170.315(a)(10)	Clinical decision support	190–380	1.16	6.95
170.315(a)(15)	Family health history	93–187	.57	3.42
170.315(b)(1)	Transitions of care	171–342	1.04	6.26
170.315(e)(1)	View, download, and transmit to third party	126–252	.77	4.61
170.315(f)(3)	Transmission to public health agencies—syndromic surveillance.	141–282	.86	5.16
Total			5.55	33.32

Unchanged Certification Criteria

TABLE 11—2015 EDITION UNCHANGED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(a)(1)	CPOE—medications	25–50	.06	.31
170.315(a)(3)	CPOE—radiology/imaging	25–50	.06	.31
170.315(a)(4)	Drug-drug, drug-allergy interaction checks	25–50	.06	.31
170.315(a)(6)	Vital signs, body mass index, and growth charts	25–50	.06	.31

TABLE 11—2015 EDITION UNCHANGED EHR CERTIFICATION CRITERIA: LEVEL 2 EFFORT—Continued

Regulation section	Title of regulation paragraph	Estimated number of EHR technologies to be developed with this capability	Average development and preparation costs—low ($M)	Average development and preparation costs—high ($M)
170.315(a)(7)	Problem list	25–50	.06	.31
170.315(a)(8)	Medication list	25–50	.06	.31
170.315(a)(9)	Medication allergy list	25–50	.06	.31
170.315(a)(12)	Drug formulary check	25–50	.06	.31
170.315(a)(13)	Smoking status	25–50	.06	.31
170.315(a)(14)	Image results	25–50	.06	.31
170.315(a)(16)	Patient list creation	25–50	.06	.31
170.315(a)(18)	Electronic medication administration record	25–50	.06	.31
170.315(a)(19)	Advance directives	25–50	.06	.31
170.315(b)(3)	Electronic prescribing	25–50	.06	.31
170.315(c)(1)	Clinical quality measures—capture and export	25–50	.06	.31
170.315(c)(2)	Clinical quality measures—import and calculate	25–50	.06	.31
170.315(c)(3)	Clinical quality measures—electronic submission	25–50	.06	.31
170.314(d)(1)	Authentication, access control, and authorization	25–50	.06	.31
170.315(d)(3)	Audit report	25–50	.06	.31
170.315(d)(4)	Amendments	25–50	.06	.31
170.315(d)(5)	Automatic log-off	25–50	.06	.31
170.315(d)(6)	Emergency access	25–50	.06	.31
170.315(d)(7)	End-user device encryption	25–50	.06	.31
170.315(d)(8)	Integrity	25–50	.06	.31
170.315(d)(9)	Accounting of disclosures	25–50	.06	.31
170.315(e)(3)	Secure messaging	25–50	.06	.31
170.315(f)(1)	Immunization information	25–50	.06	.31
170.315(f)(5)	Cancer case information	25–50	.06	.31
170.315(g)(1)	Automated numerator recording	25–50	.06	.31
170.315(g)(2)	Automated measure calculation	25–50	.06	.31
170.315(g)(3)	Safety-enhanced design	25–50	.06	.31
170.315(g)(4)	Quality systems management	25–50	.06	.31
Total			1.92	9.92

ii. Overall Development and Preparation Costs Over a Two-Year Period

In total, we estimate the overall costs to develop and prepare EHR technology for certification over a two-year period to be $19.65 million to $93.26 million, with a cost mid-point of approximately $56.46 million. Evenly distributed over calendar years 2014 and 2015, the cost range would be $9.82 million to $46.63 per year with an annual cost mid-point of approximately $28.23. We project these costs to be evenly distributed over calendar years 2014 and 2015 for the following reasons:

- We expect a subsequent 2015 Edition final rule to be published in the summer of 2014.
- We expect a 2017 Edition proposed rule to be published in the fall 2014 and a 2017 Edition final rule to be published approximately by summer 2015.
- We assume a number of developers will develop and prepare EHR technology for testing and certification in the last half of 2014 so that the EHR technology can be implemented and used to meet the current CEHRT definition.
- We expect development and preparation in 2015 to continue at a similar pace until a 2017 Edition final rule is published and testing and certification to the 2017 Edition certification criteria can begin.
- We expect that EHR technology developers will shift development and preparation of their EHR technology to meeting the 2017 Edition because it is expected to become the basis for meeting the CEHRT definition in future years.
- While we could foresee EHR technology developers possibly shifting to development and preparation of their EHR technology to meet the 2017 Edition as soon as the 2017 Edition proposed rule is issued (fall 2014), we could also foresee HIT developers continuing development and preparation of their HIT to meet the 2015 Edition and then pursuing gap certification to the 2017 Edition.

Table 12 below represents the costs attributable to this proposed rule distributed as follows: 50% for 2014 and 50% for 2015. The dollar amounts expressed in Table 12 are expressed in 2014 dollars.

TABLE 12—DISTRIBUTED TOTAL PREPARATION COSTS FOR EHR TECHNOLOGY DEVELOPERS

[(Two-year period)—totals rounded]

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2014	50	9.82	46.63	28.23
2015	50	9.82	46.63	28.23

TABLE 12—DISTRIBUTED TOTAL PREPARATION COSTS FOR EHR TECHNOLOGY DEVELOPERS—Continued

[(Two-year period)—totals rounded]

Year	Ratio (percent)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2-Year Totals		19.65	93.26	56.46

iii. Testing and Certification Costs for the 2015 Edition

In the regulatory impact analysis of the Permanent Certification Program final rule, we estimated the costs for testing and certification of EHR technologies that would be used for providers to attempt to achieve MU Stages 1–3.[164] These costs were based on a two-year rulemaking cycle for the CEHRT definition and each MU Stage. We believe the costs we attributed to testing and certification of EHR technologies in support of MU Stage 2 in the Permanent Certification Program final rule would encompass the actual testing and certification of EHR technologies to both the 2014 and 2015 Editions. This assessment is based on the number of EHR technologies currently certified to the 2014 Edition and our projections in this proposed rule for the number of EHR technologies that would likely be tested and certified to the 2015 Edition EHR certification criteria. Further, we note that the estimated costs in the Permanent Certification Program final rule included costs for surveillance of EHR technologies and also estimated the costs for testing and certification above what we understand are the cost ranges charged by ONC–ACBs today. We welcome comments on our determination and our cost estimates.

b. Benefits

We believe that there will be several significant benefits that may arise from this proposed rule for patients, health care providers, and EHR technology developers. Our proposals incorporate stakeholder feedback on particular 2014 Edition issues identified as unnecessarily impeding innovation. Our proposed revisions also seek to continue to improve EHR technology's interoperability through the adoption of updated standards and implementation specifications. Furthermore, our proposal to separate ''content'' and ''transport'' capabilities in 2015 Edition transitions of care certification criterion (compared to how the 2014 Edition version is structured) is aimed at significantly improving the market availability of electronic health information exchange services. And our proposed 2015 Edition ''view, download, transmit to 3rd party'' certification criterion includes a greater focus on enabling a patient to choose where they want to send their health information. We believe these proposed revisions would open new market opportunities for EPs, EHs, and CAHs to select best of breed products as well as reduce EHR technology developer burdens related to certification. Our proposals and requests for comment in this proposed rule also signal to the industry the future direction we hope to go with our certification criteria and certification program. This advanced visibility can better assist EHR technology developers plan for the future.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities.

The Small Business Administration (SBA) establishes the size of small businesses for federal government programs based on average annual receipts or the average employment of a firm. While EHR technology developers that pursue certification under the ONC HIT Certification Program represent a small segment of the overall information technology industry, we believe that the entities impacted by this proposed rule most likely fall under the North American Industry Classification System (NAICS) code 541511 ''Custom Computer Programming Services'' specified at 13 CFR 121.201 where the SBA publishes ''Small Business Size Standards by NAICS Industry.'' The SBA size standard associated with this NAICS code is set at $25 million in annual receipts[165] which ''indicates the maximum allowed for a concern and its affiliates to be considered small entities.''

Based on our analysis, we believe that there is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard, but note that the available data does not show how many of these entities will develop a EHR product that will be certified to the 2015 Edition certification criteria under the ONC HIT Certification Program. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many EHR technology developers that pursue certification under the ONC HIT Certification Program are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of these EHR technology developers to correlate to the SBA size standard. However, although not correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of EHR technology developers that have had Complete EHRs and/or EHR Modules certified to the 2011 Edition EHR certification criteria have less than 51 employees.[166]

We estimate that this proposed rule would have effects on EHR technology developers that are likely to pursue certification under the ONC HIT Certification Program, some of which may be small entities. However, we believe that we have proposed the minimum amount of requirements necessary to accomplish our policy goals, including a reduction in regulatory burden and additional flexibility for the regulated community, and that no additional appropriate regulatory alternatives could be developed to lessen the compliance burden associated with this proposed rule. We note that this proposed rule does not impose the costs cited in the regulatory impact analysis as compliance costs, but rather as

[164] 76 FR 1318.

[165] The SBA references that annual receipts means ''total income'' (or in the case of a sole proprietorship, ''gross income'') plus ''cost of goods sold'' as these terms are defined and reported on Internal Revenue Service tax return forms. *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

[166] We hope to update this information in a subsequent final rule based on data obtained regarding certification to the 2014 Edition.

investments which these EHR technology developers voluntarily take on and expect to recover with an appropriate rate of return. Accordingly, we do not believe that the proposed rule will create a significant impact on a substantial number of small entities, but request comment on whether there are small entities that we have not identified that may be affected in a significant way by this proposed rule. Additionally, the Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

3. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Nothing in this proposed rule imposes substantial direct compliance costs on state and local governments, preempts state law or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the standards, implementation specifications, or certification criteria that we propose for adoption.

4. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately $141 million. This proposed rule will not impose an unfunded mandate on State, local, and tribal governments or on the private sector that will reach the threshold level.

C. Request for Comments on 2017 Impact Analysis Methods

In response to ONC's 2011 Edition and 2014 Edition rulemakings some stakeholders have suggested that we underestimate the burden associated with developing EHR technology to meet the certification criteria. Yet those stakeholders have not provided data or alternative(s) to the methods that we have used in our rules to prepare the best estimate we can. In our 2014 Edition Final Rule and in this proposed rule, we use a three level approach with hour ranges and multiply those ranges by the number of EHR technologies we expect to be developed to be tested and certified to those criteria. This proposed rule and the 2014 Edition Final Rule's impact analysis represented a significant improvement on our 2011 Edition's impact analysis due to the fact that we now have data on EHR technology certified to the criteria we had adopted.

That being said, we believe we can do a better job estimating our certification criteria impacts so long as commenters, especially EHR technology developers, can provide company-specific responses with estimates or ranges. To facilitate more streamlined industry feedback, and in turn more accurate estimates, we are considering using the following template in our 2017 Edition rulemaking that would be part of each certification criterion's preamble discussion. We would pre-populate this template in the 2017 Edition proposed rule with our burden/compliance estimates and enable commenters to compare our estimates to their own. The proposed estimates would also reflect whether the certification criterion's capabilities had previously been adopted. We believe that this level of feedback could then be used to more accurately reflect our regulation's potential impacts. We propose to use a template that splits out specific actions/specific technical capabilities as follows. We also expect have a ''level of effort'' multiplier/coefficient in the third column to account for instances where we would assume that EHR technology developers have already invested time and resources toward implementing a regulatory requirement. This multiplier would range from zero to one (or 0% to 100%). For instance, with respect to a certification criterion that remains the same between editions, we may put a zero since our rule would not require any additional effort from the EHR technology developer to meet the criterion. Similarly, for certification criteria that only have a specific capability revised (e.g., the proposed 2015 Edition ''demographics'' certification criterion), we could put zeros for most rows and .25 for the proposed updated language standard to account for the one change to an otherwise largely unmodified certification criterion.

Certification criterion	First-time development effort for regulatory compliance	Multiplier for subsequent development level of effort
Requirements/Design Specification	X Hours	(0 to 1).
Capability 1 Total	XX Hours	(0 to 1).
Sub-Capability 1–1	X Hours	(0 to 1).
Sub-Capability 1–2	X Hours	(0 to 1).
Capability 2 Total	XX Hours	(0 to 1).
Capability 2–1	X Hours	(0 to 1).
Capability 2–2	X Hours	(0 to 1).

We also encourage stakeholders to review the HIMSS EHRA's development estimate presentation, delivered to the Meaningful Use Workgroup of the HITPC on September 24, 2013 and available here: *http://www.healthit.gov/facas/calendar/2013/09/24/policy-meaningful-use-wg*. The EHRA's model can serves as another point of input for commenters to consider in suggesting alternative methods for our impact analysis.

Finally, we seek comment on whether this modified approach would be beneficial and which methodology stakeholders believe we should consider. We also ask stakeholders to comment on their ability and willingness to complete company level estimates in conjunction with the general comments in response to the NPRM.

OMB reviewed this proposed rule.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and

recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is proposed to be amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 2. In § 170.102:

■ a. Remove the ''2011 Edition EHR certification criteria'' and ''Complete EHR, 2011 Edition'' definitions;

■ b. Add in alphanumeric order the definitions for ''2015 Edition EHR certification criteria,'' ''Device Identifier,'' ''Implantable Device,'' ''Production Identifier,'' and ''Unique Device Identifier;'' and

■ c. Revise the definitions for ''Base EHR,'' paragraph (2) of ''Certified EHR Technology,'' ''EHR Module'', and paragraph (6) of the ''Common MU Data Set'' definition to read as follows:

§ 170.102 Definitions.

* * * * *

2015 Edition EHR certification criteria means the certification criteria at § 170.315.

Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources;

(v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

(3) Has been certified to the certification criteria adopted by the Secretary at:

(i) Section 170.314(a)(1); or § 170.315(a)(1), (2), or (3);

(ii) Section 170.314(a)(3) or § 170.315(a)(5);

(iii) Section 170.314(a)(5) or § 170.315(a)(7);

(iv) Section 170.314(a)(6) or § 170.315(a)(8);

(v) Section 170.314(a)(7) or § 170.315(a)(9);

(vi) Section 170.314(a)(8) or § 170.315(a)(10);

(vii) Both § 170.314(b)(1) and (2); or, both § 170.315(b)(1) and § 170.315(h)(1); or § 170.314(b)(1) and (2) combined with either § 170.315(b)(1) or § 170.315(h)(1), or both § 170.315(b)(1) and § 170.315(h)(1);

(viii) Section 170.314(b)(7) or § 170.315(b)(6);

(ix) Section 170.314(c)(1) or § 170.315(c)(1);

(x) Section 170.314(c)(2) or § 170.315(c)(2);

(xi) Section 170.314(c)(3) or § 170.315(c)(3);

(xii) Section 170.314(d)(1) or § 170.315(d)(1);

(xiii) Section 170.314(d)(2) or § 170.315(d)(2);

(xiv) Section 170.314(d)(3) or § 170.315(d)(3);

(xv) Section 170.314(d)(4) or § 170.315(d)(4);

(xvi) Section 170.314(d)(5) or § 170.315(d)(5);

(xvii) Section 170.314(d)(6) or § 170.315(d)(6);

(xviii) Section 170.314(d)(7) or § 170.315(d)(7); and

(xix) Section 170.314(d)(8) or § 170.315(d)(8).

(4) Has been certified to the certification criteria at § 170.314(c)(1) and (2) or § 170.315(c)(1) and (2):

(i) For no fewer than 9 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 clinical quality measures from the recommended core set identified by CMS; or

(ii) For no fewer than 16 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals.

* * * * *

Certified EHR Technology means:

* * * * *

(2) For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 or 2015 Edition EHR certification criteria that has:

(i) The capabilities required to meet the Base EHR definition; and

(ii) All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

Common MU Data Set

* * * * *

(6) Preferred language. (i) The standard specified in § 170.207(g)(1) for certification to the 2014 Edition EHR certification criteria.

(ii) The standard specified in § 170.207(g)(2) for certification to the 2015 Edition EHR certification criteria.

* * * * *

Device Identifier is defined as it is in 21 CFR 801.3.

* * * * *

EHR Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

(1) *MU EHR Module* means any service, component, or combination thereof that is designed for purposes of the EHR Incentive Programs and can meet the requirements of at least one certification criterion adopted by the Secretary as part of the 2015 Edition EHR certification criteria.

(2) *Non-MU EHR Module* means any service, component, or combination thereof that is designed for any purpose other than the EHR Incentive Programs and can meet the requirements of at least one certification criterion adopted by the Secretary as part of the 2015 Edition EHR certification criteria.

* * * * *

Implantable Device is defined as it is in 21 CFR 801.3.

* * * * *

Production Identifier is defined as it is in 21 CFR 801.3.

* * * * *

Unique Device Identifier is defined as it is in 21 CFR 801.3.

■ 3. In § 170.202, republish the introductory text and add paragraphs (d) and (e) to read as follows:

§ 170.202 Transport standards.

The Secretary adopts the following transport standards:

* * * * *

(d) *Standard.* ONC Implementation Guide for Delivery Notification in Direct.

(e) *Standard.* ONC Implementation Guide for Direct Edge Protocols.

■ 4. Amend § 170.204 by—

■ A. Republishing the introductory text;

■ B. Revising paragraph (a);

■ C. Revising paragraph (b)(2) and adding paragraph (b)(3); and

■ D. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility.* (1) *Standard.* Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).

(2) *Standard.* Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance.

(b) * * *

(2) *Implementation specifications.* HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Draft Standard for Trial Use, Release 1.

(3) *Implementation specifications.* HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.

* * * * *

(d) *Decision Support. Standard.* HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide.

(e) *Decision Support. Standard.* HL7 Decision Support Service Implementation Guide.

■ 5. Amend § 170.205 by—

■ A. Republishing the introductory text;

■ B. Adding paragraph (a)(4);

■ C. Removing and reserving paragraphs (b)(1), (c), and (d)(1);

■ D. Adding paragraphs (d)(4) and (5);

■ E. Removing and reserving paragraphs (e)(1), and (e)(2);

■ F. Adding paragraph (e)(4);

■ G. Removing and reserving paragraph (f);

■ H. Revising paragraphs (g), (i), and (j); and

■ I. Adding paragraphs (l) and (m).

The revisions and additions read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) * * *

(4) *Standard.* HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.0. The use of the ''unstructured document'' document-level template is prohibited.

(b) * * *

(1) [Reserved]

* * * * *

(c) [Reserved]

(d) * * *

(1) [Reserved]

* * * * *

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, and Inpatient Settings, Release 1.9.

(5) HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299).

(e) * * *

(1) [Reserved]

(2) [Reserved]

* * * * *

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5.

(f) [Reserved]

(g) *Electronic transmission of lab results to public health agencies.* (1) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification (incorporated by reference in § 170.299).

(2) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Draft Standard for Trial Use, Release 2.

* * * * *

(i) *Cancer information.* (1) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0 (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.1.

(j) *Electronic incorporation and transmission of lab results.* (1) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 (US Realm) (S&I Framework LRI) with Errata.

* * * * *

(l) *Laboratory orders.* (1) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR.

(2) [Reserved]

(m) *Family health history.* (1) HL7 Version 3 Standard: Clinical Genomics; Pedigree (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability.

(2) [Reserved]

■ 6. Amend § 170.207 by—

■ A. Republishing the introductory text;

■ B. Removing and reserving paragraphs (a)(1), (a)(2), (b)(1), (c)(1), (d)(1), and (e)(1); and

■ C. Revising paragraph (g).

The revisions read as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) * * *

(1) [Reserved]

(2) [Reserved]

* * * * *

(b) * * *

(1) [Reserved]

* * * * *

(c) * * *

(1) [Reserved]

* * * * *

(d) * * *

(1) [Reserved]

* * * * *

(e) * * *

(1) [Reserved]

* * * * *

(g) *Preferred language.* (1) *Standard.* As specified by the Library of Congress, ISO 639–2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639–1 (incorporated by reference in § 170.299).

(2) *Standard.* As specified by the Library of Congress, ISO 639–2.

* * * * *

§ 170.210 [Amended]

■ 7. In § 170.210, remove and reserve paragraphs (a)(2) and (b).

■ 8. Add § 170.212 to read as follows:

§ 170.212 Performance standards for health information technology.

The Secretary adopts the following performance standards for health information technology:

(a) EHR technology must successfully electronically process documents validly formatted in accordance with the standard specified in § 170.205(a)(4) no less than 95% of the time.

(b) [Reserved]

■ 9. In § 170.300, revise paragraph (d) to read as follows:

§ 170.300 Applicability.

* * * * *

(d) In §§ 170.314 and 170.315, all certification criteria and all capabilities specified within a certification criterion have general applicability (i.e., apply to both ambulatory and inpatient settings) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

(1) *Inpatient setting only* means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an inpatient setting.

(2) *Ambulatory setting only* means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an ambulatory setting.

§ 170.302 [Removed and Reserved]

■ 10. Remove and reserve § 170.302.

§ 170.304 [Removed and Reserved]

■ 11. Remove and reserve § 170.304.

§ 170.306 [Removed and Reserved]

■ 12. Remove and reserve § 170.306.

■ 13. In § 170.314:

■ A. In § 170.314(a)(3)(i)(B), remove ''§ 170.207(g)'' and add in its place ''§ 170.207(g)(1)'';

■ B. In § 170.314(b)(5)(i)(A)(1), remove ''§ 170.205(j)'' and add in its place ''§ 170.205(j)(1)'';

■ C. In § 170.314(b)(6), remove ''§ 170.205(j)'' and add in its place ''§ 170.205(j)(1)'';

■ D. In § 170.314(e)(1)(i)(A), remove ''§ 170.204(a)'' and add in its place ''§ 170.204(a)(1)'';

■ E. In § 170.314(f)(4)(i), remove ''§ 170.205(g)'' and add in its place ''§ 170.205(g)(1)'';

■ F. In § 170.314(f)(6), remove ''§ 170.205(i)'' and add in its place '' § 170.205(i)(1)'';

and

■ G. Revise § 170.314(f)(3) and (g)(1).

The revisions read as follows:

§ 170.314 2014 Edition electronic health record certification criteria.

* * * * *

(f) * * *

(3) * * *

(i) *Ambulatory setting only.* The standard specified in § 170.205(d)(2), (d)(5), or (k).

(B) *Optional.* The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(ii) *Inpatient setting only.* The standard (and implementation specifications) specified in § 170.205(d)(4).

* * * * *

(g) * * *

(1) *Optional—Automated numerator recording.* For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

* * * * *

■ 14. Add § 170.315 as follows:

§ 170.315 2015 Edition electronic health record certification criteria.

The Secretary adopts the following certification criteria for EHR technology certification. EHR technology must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Clinical.* (1) *Computerized provider order entry—medications.* Enable a user to electronically record, change, and access medication orders.

(2) *Computerized provider order entry—laboratory.* (i) Enable a user to electronically record, change, and access laboratory orders.

(ii) *Ambulatory setting only.* Enable a user to electronically create laboratory orders for electronic transmission:

(A) With all the information for a test requisition as specified at 42 CFR 493.1241(c)(1) through (c)(8); and

(B) In accordance with the standard specified at § 170.205(l)(1) and, at a minimum the version of the standard at § 170.207(c)(2).

(3) *Computerized provider order entry—radiology/imaging.* Enable a user to electronically record, change, and access radiology and imaging orders.

(4) *Drug-drug, drug-allergy interaction checks.* (i) *Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) *Adjustments.* (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(5) *Demographics.* (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.

(ii) *Inpatient setting only.* Enable a user to electronically record, change, and access the preliminary cause of death and date of death in the event of a mortality.

(6) *Vital signs, body mass index, and growth charts.* (i) *Vital signs.* Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.

(ii) *Calculate body mass index.* Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) *Optional—Plot and display growth charts.* Plot and electronically display, upon request, growth charts for patients.

(7) *Problem list.* Enable a user to electronically record, change, and access a patient's active problem list:

(i) *Ambulatory setting.* Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) *Inpatient setting.* For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

(8) *Medication list.* Enable a user to electronically record, change, and access a patient's active medication list as well as medication history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(9) *Medication allergy list.* Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(10) *Clinical decision support.* (i) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) At least one demographic specified in paragraph (a)(5)(i) of this section;

(E) Laboratory tests; and

(F) Vital signs.

(ii) *Linked referential clinical decision support.* (A) EHR technology must be able to:

(*1*) Electronically identify for a user diagnostic and therapeutic reference information; or

(*2*) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3).

(B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

(iii) *Clinical decision support configuration.* (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) EHR technology must enable interventions to be electronically triggered:

(*1*) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.

(*2*) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section.

(*3*) *Ambulatory setting only.* When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(*1*) of this section.

(iv) *Automatically and electronically interact.* Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) *Source attributes.* Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:

(*1*) Bibliographic citation of the intervention (clinical research/guideline);

(*2*) Developer of the intervention (translation from clinical research/guideline);

(*3*) Funding source of the intervention development technical implementation; and

(*4*) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) *Decision support—knowledge artifact.* Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at § 170.204(d).

(vii) *Decision support—service.* Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at § 170.204(e).

(11) *Electronic notes.* Enable a user to electronically:

(i) Record, change, and access electronic notes; and

(ii) Search within and across electronic notes stored within EHR technology.

(12) *Drug-formulary checks.* EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

(13) *Smoking status.* Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

(14) *Image results.* Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

(15) *Family health history.* Enable a user to electronically record, change, and access a patient's family health history according to the standard and implementation specification specified at § 170.205(m)(1).

(16) *Patient list creation.* Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

(i) Problems;

(ii) Medications;

(iii) Medication allergies;

(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;

(v) Laboratory tests and values/results; and

(vi) *Ambulatory setting only.* Patient communication preferences.

(17) *Patient-specific education resources.* EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests:

(i) In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (3); and

(ii) By any means other than using the standard specified in § 170.204(b).

(18) *Inpatient setting only—electronic medication administration record.* (i) In combination with an assistive technology that provides automated information on the ''rights'' specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):

(A) *Right patient.* The patient to whom the medication is to be administered matches the medication to be administered.

(B) *Right medication.* The medication to be administered matches the medication ordered for the patient.

(C) *Right dose.* The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) *Right route.* The route of medication delivery matches the route specified in the medication order.

(E) *Right time.* The time that the medication was ordered to be administered compared to the current time.

(ii) *Right documentation.* Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user

identification when a medication is administered.

(19) *Inpatient setting only—advance directives.* Enable a user to electronically record whether a patient has an advance directive.

(20) *Implantable device list.* (i) Enable a user to electronically access and view a list of Unique Device Identifiers and other relevant information associated with a patient's Implantable Device(s).

(ii) Enable a user to electronically record in a patient's Implantable Device list the following information at the time the Implantable Device is implanted or removed:

(A) The Unique Device Identifier associated with the Implantable Device; and

(B) Other relevant information about the Implantable Device or procedure.

(iii) For each Unique Device Identifier in a patient's Implantable Device list, allow a user to separately access and view electronically the Device Identifier and Production Identifier portions of the Unique Device Identifier.

(b)*Care coordination. (1) Transitions of care. (i) Send and receive via edge protocol.* EHR technology must be able to electronically:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at § 170.202(e) and that leads to such summaries being processed by a service that has implemented the standard specified in § 170.202(a); and

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at § 170.202(e) from a service that has implemented the standard specified in § 170.202(a).

(ii) *Receiving accuracy.* EHR technology must meet or exceed the standard specified at § 170.212(a)

(iii) *Display.*

(A) EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1) through (4).

(B) *Section views.* Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3).

(iv) *Create.* (A) Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(4) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(*1*) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3);

(*2*) *Immunizations.* The standard specified in § 170.207(e)(2);

(*3*) Cognitive status;

(*4*) Functional status;

(*5*) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information;

(*6*) *Inpatient setting only.* Discharge instructions; and

(*7*) Unique Device Identifier(s) for a patient's Implantable Device(s).

(B) *Patient matching data quality.* EHR technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(*1*) *Data.* first name, last name, middle name (or middle initial in cases where only it exists/is used), suffix, date of birth, place of birth, maiden name, current address, historical address, phone number, and sex.

(*2*) *Constraint.* Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(*3*) *Constraint.* Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, Ph.D., ESQ). If no suffix exists, the field should be entered as null.

(*4*) *Constraint.* Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(*5*) *Constraint.* Represent current and historical address information, including the street address, city, state, zip code, according to the United States Postal Service format;

(*6*) *Constraint.* Represent phone number (home, business, cell) in the ITU format specified in ITU–T E.123 and ITU–T E.164. If multiple phone numbers are present, all should be included.

(*7*) *Constraint.* Represent sex according to the HL7 Version 3 ValueSet for Administrative Gender.

(2) *Clinical information reconciliation and incorporation.* (i) *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(4), EHR technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(ii) *Reconciliation.* Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(A) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;

(B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;

(C) Enable a user to review and validate the accuracy of a final set of data; and

(D) Upon a user's confirmation, automatically update the list, and electronically incorporate the following data expressed according to the specified standard(s):

(*1*) *Medications.* At a minimum, the version of the standard specified in § 170.207(d)(2);

(*2*) *Problems.* At a minimum, the version of the standard specified in § 170.207(a)(3);

(*3*) *Medication allergies.* At a minimum, the version of the standard specified in § 170.207(d)(2).

(3) *Electronic prescribing.* Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

(i) The standard specified in § 170.205(b)(2); and

(ii) At a minimum, the version of the standard specified in § 170.207(d)(2).

(4) *Incorporate laboratory tests and values/results.* (i) *Receive results.* (A) *Ambulatory setting only.* (*1*) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(*2*) Electronically display the tests and values/results received in human readable format.

(B) *Inpatient setting only.* Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such

tests and values/results in human readable format.

(ii) Electronically display the test report information:

(A) Specified in 42 CFR 493.1291(a)(1) through (a)(3) and (c)(1) through (c)(7);

(B) Related to reference values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

(5) *Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers.* EHR technology must be able to electronically create laboratory test reports for electronic transmission: (i) That includes the information:

(A) For a test report as specified in 42 CFR 493.1291(a)(1) through (a)(3) and (c)(1) through (c)(7);

(B) Related to reference values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2); and

(ii) In accordance with the standard specified in § 170.205(j)(2) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).

(6) *Data portability.* Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(4) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) *Immunizations.* The standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status;

(v) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information;

(vi) *Inpatient setting only.* Discharge instructions; and

(vii) Unique Device Identifier(s) for a patient's Implantable Device(s).

(c) *Clinical quality measures.* (1) *Clinical quality measures—capture and export.* (i) *Capture.* For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of ''patient reason,'' ''system reason,'' or ''medical reason.''

(ii) *Export.* EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

(2) *Clinical quality measures—import and calculate.* (i) *Import.* EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).

(ii) *Calculate.* EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

(3) *Clinical quality measures—electronic submission.* Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at § 170.205(h) and (k); and

(ii) That can be electronically accepted by CMS.

(4) *Clinical quality measures—patient population filtering.* EHR technology must be able to record structured data for the purposes of being able to filter CQM results to create different patient population grouping by one or a combination of the following patient characteristics:

(i) practice site and address;

(ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;

(iii) Diagnosis;

(iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and

(v) Demographics including age, sex, preferred language, education level, and socioeconomic status.

(d) *Privacy and security.* (1) *Authentication, access control, and authorization.* (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

(2) *Auditable events and tamper-resistance.* (i) *Record actions.* EHR technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1); and

(B) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).

(ii) *Default setting.* EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B).

(iii) *Prevent disabling.* EHR technology must prevent all users from being able to disable the capabilities specified in paragraphs (d)(2)(i)(A) and (B) of this section through the EHR technology.

(iv) *Audit log protection.* Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) *Detection.* EHR technology must be able to detect whether the audit log has been altered.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).

(4) *Amendments.* Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.

(i) *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) *Denied amendment.* For a denied amendment, at a minimum, append the request and denial of the request to the

affected record or include a link that indicates this information's location.

(5) *Automatic log-off.* Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion. (i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).

(B) *Default setting.* EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(e) *Patient engagement.* (1) *View, download, and transmit to 3rd party.* (i) Patients (and their authorized representatives) must be able to use EHR technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) *View.* Patients (and their authorized representatives) must be able to use EHR technology to electronically view in accordance with the standard adopted at § 170.204(a)(2), at a minimum, the following data:

(*1*) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(*2*) *Ambulatory setting only.* Provider's name and office contact information.

(*3*) *Inpatient setting only.* Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(B) Download.

(*1*) Patients (and their authorized representatives) must be able to use EHR technology to electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats.

(*2*) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(*i*) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(*1*) and (*2*) of this section and Unique Device Identifier(s) for a patient's implantable device(s).

(*ii*) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(*1*) and (*3*) of this section and Unique Device Identifier(s) for a patient's Implantable Device(s).

(*3*) *Inpatient setting only.* Patients (and their authorized representatives) must be able to electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(*1*) Enter a 3rd party destination of their choice to electronically transmit:

(*i*) The ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).

(*ii*) *Inpatient setting only.* Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(*2*) Accomplish a transmission of their ambulatory summary or inpatient summary through a method that conforms to the standard specified at § 170.202(e) and that leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(ii) *Activity history log.* (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(*1*) The action(s) (i.e., view, download, transmission) that occurred;

(*2*) The date and time each action occurred in accordance with the standard specified at § 170.210(g);

(*3*) The user who took the action; and

(*4*) The addressee to whom an ambulatory summary or inpatient summary was transmitted and whether that transmission was successful (or failed).

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

(2) *Ambulatory setting only—clinical summary.* (i) *Create.* Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(4).

(ii) *Customization.* Enable a user to customize the data included in the clinical summary.

(iii) *Minimum data from which to select.* EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set);

(B) *Medications administered during the visit.* At a minimum, the version of the standard specified in § 170.207(d)(2);

(C) *Immunizations administered during the visit.* At a minimum, the version of the standard specified in § 170.207(e)(2);

(D) *Diagnostic tests pending and future scheduled tests.* At a minimum, the version of the standard specified in § 170.207(c)(2);

(E) The provider's name and office contact information; date and location of visit; reason for visit; clinical instructions; future appointments;

referrals to other providers; and recommended patient decision aids; and

(F) Unique Device Identifier(s) for a patient's Implantable Device(s).

(3) *Ambulatory setting only—secure messaging.* Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(f) *Public health.* (1) *Immunization information.* Enable a user to electronically record, change, and access immunization information.

(2) *Transmission to immunization registries.* EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(4); and

(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).

(3) *Transmission to public health agencies—syndromic surveillance.* EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) *Ambulatory setting only.* (A) The standard specified in § 170.205(d)(2), (d)(5), or (k).

(B) *Optional.* The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(ii) *Inpatient setting only.* The standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(4) *Inpatient setting only—transmission of reportable laboratory tests and values/results.* EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(5) *Ambulatory setting only—cancer case information.* Enable a user to electronically record, change, and access cancer case information.

(6) *Ambulatory setting only—transmission to cancer registries.* EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(g) *Utilization.* (1) *Automated numerator recording.* For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(3) *Safety-enhanced design.* User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.315(a)(1) through (4), (8) through (10), and (18) and (b)(2) and (3).

(4) *Quality management system.* For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.

(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.

(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

(5) *Non-percentage-based measures use report.* (i) For each capability included in EHR technology that is also associated with a meaningful use objective and measure that is not percentage-based (except for the capabilities specified in § 170.315(a)(12), (b)(1), and (d)) electronically record evidence that a user used or interacted with the capability and the date and time that such use or interaction occurred, in accordance with the standard specified at § 170.210(g).

(ii) Enable a user to electronically create a report of the information recorded as part of paragraph (g)(5)(i) of this section for the user's identified Medicare or Medicaid EHR Incentive Program reporting period.

(h) *Transmission.* (1) *Transmit—Applicability Statement for Secure Health Transport.* Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(a).

(2) *Transmit—Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging.* Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(b).

(3) *Transmit—SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.* Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(c).

(4) *Transmit—Applicability Statement for Secure Health Transport and Delivery Notification in Direct.* Enable health information to be electronically transmitted in accordance with the standard specified in § 170.202(d).

Subpart D—[Removed and Reserved]

■ 15. Remove and reserve subpart D, consisting of §§ 170.400 through 170.499.

■ 16. Revise § 170.501 to read as follows:

§ 170.501 Applicability.

(a) This subpart establishes the processes that applicants for ONC–ACB status must follow to be granted ONC–ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC–ACB status; the requirements that ONC–ACBs must follow to maintain ONC–ACB status; and the requirements of ONC–ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization

under the ONC HIT Certification Program as well as certain ongoing responsibilities for an ONC–AA.

(b) References to the term Complete EHR and Complete EHR certification throughout this subpart do not apply to certification in accordance with the 2015 Edition EHR certification criteria and any subsequent edition of certification criteria adopted by the Secretary under subpart C of this part.

■ 17. Amend § 170.502 by adding the definition ''Certification Package,'' to read as follows:

* * * * *

Certification Package means an identified set of certification criteria adopted by the Secretary in subpart C of this part that represent a specific grouping of capabilities.

(1) *2015 Edition Care Coordination Package* includes, at a minimum, § 170.315(b)(1) and (2).

(2) *2015 Edition Patient Engagement Package* includes, at a minimum, § 170.315(e)(1) and (3).

* * * * *

■ 18. In § 170.503, revise paragraphs (b)(1) and (e)(2) to read as follows:

§ 170.503 Requests for ONC–AA status and ONC–AA ongoing responsibilities.

* * * * *

(b) * * *

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011 (incorporated by reference in § 170.599) and experience evaluating the conformance of certification bodies to ISO/IEC 17065.

* * * * *

(e) * * *

(2) Verify that the certification bodies it accredits and ONC–ACBs conform to, at a minimum:

(i) For fiscal years 2014 and 2015, ISO/IEC Guide 65 (incorporated by reference in § 170.599); and

(ii) For fiscal year 2016 and subsequent years, ISO/IEC 17065.

* * * * *

■ 19. In § 170.523, republish the introductory text, revise paragraph (k)(1)(iii), and add paragraphs (k)(1)(iv) and (l) to read as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

* * * * *

(k) * * *

(1) * * *

(iii) Any additional types of costs that an EP, EH, or CAH would pay to implement the Complete EHR's or EHR Module's capabilities in order to attempt to meet meaningful use objectives and measures. Beginning with EHR technology certified to the 2015 Edition EHR certification criteria, any additional types of costs that an EP, EH, or CAH would pay to implement the MU EHR Module's capabilities in order to attempt to meet meaningful use objectives and measures. EHR technology self-developers are excluded from the requirements of this paragraph.

(iv) If an EHR Module developer chooses to represent that an EHR Module satisfies a certification package(s) as defined in § 170.502 of this subpart, such representations must be accurate.

* * * * *

(l) Display the ONC Certified HIT Certification and Design Mark on all certifications issued under the ONC HIT Certification Program in a manner that complies with the Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark, and ensure that use of the mark by HIT developers whose products are certified under the ONC HIT Certification Program is compliant with the Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark.

■ 20. In § 170.550, remove and reserve paragraph (e), revise paragraph (f) introductory text and (f)(1), redesignate paragraph (g) as (h), and add a new paragraph (g) to read as follows:

§ 170.550 EHR Module certification.

* * * * *

(e) [Reserved]

(f) When certifying an EHR Module to the 2014 Edition EHR certification criteria, an ONC–ACB must certify the EHR Module in accordance with the certification criteria at:

(1) Section 170.314(g)(1) or (g)(2) if the EHR Module has capabilities presented for certification that would support a meaningful use objective with a percentage-based measure;

* * * * *

(g) When certifying an EHR Module to the 2015 Edition EHR certification criteria, an ONC–ACB must certify the EHR Module in accordance with the certification criteria at:

(1) Section 170.315(g)(1) or (g)(2) if the MU EHR Module has capabilities presented for certification that would support a meaningful use objective with a percentage-based measure;

(2) Section 170.315(g)(3) if the EHR Module is presented for certification to one or more listed certification criteria in § 170.315(g)(3);

(3) Section 170.315(g)(4); and

(4) Section 170.315(g)(5) if the MU EHR Module has capabilities presented for certification that would support a meaningful use objective with a non-percentage-based measure.

* * * * *

Dated: February 18, 2014.

Kathleen Sebelius,

Secretary.

[FR Doc. 2014–03959 Filed 2–21–14; 4:15 pm]

BILLING CODE 4150–45–P

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No. 38 February 26, 2014

Part III

The President

Notice of February 25, 2014—Continuation of the National Emergency With Respect to Cuba and of the Emergency Authority Relating to the Regulation of the Anchorage and Movement of Vessels

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Presidential Documents

Title 3—

The President

Notice of February 25, 2014

Continuation of the National Emergency With Respect to Cuba and of the Emergency Authority Relating to the Regulation of the Anchorage and Movement of Vessels

On March 1, 1996, by Proclamation 6867, a national emergency was declared to address the disturbance or threatened disturbance of international relations caused by the February 24, 1996, destruction by the Cuban government of two unarmed U.S.-registered civilian aircraft in international airspace north of Cuba. On February 26, 2004, by Proclamation 7757, the national emergency was extended and its scope was expanded to deny monetary and material support to the Cuban government. The Cuban government has not demonstrated that it will refrain from the use of excessive force against U.S. vessels or aircraft that may engage in memorial activities or peaceful protest north of Cuba. In addition, the unauthorized entry of any U.S.-registered vessel into Cuban territorial waters continues to be detrimental to the foreign policy of the United States. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency with respect to Cuba and the emergency authority relating to the regulation of the anchorage and movement of vessels set out in Proclamation 6867 as amended by Proclamation 7757.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
February 25, 2014.

[FR Doc. 2014–04406
Filed 2–25–14; 12:30 pm]
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