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Title 3—

Memorandum of September 29, 2015

The President

Delegation of Authority Under Section 404(c) of the Child Soldiers Prevention Act of 2008**Memorandum for the Secretary of State**

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State the authority under section 404(c)(1) of the Child Soldiers Prevention Act of 2008 (22 U.S.C. 2370c-1) (CSPA), to waive the application of the prohibition in section 404(a) of the CSPA to Yemen, and to make the determinations necessary for such waiver. I hereby also delegate to the Secretary of State the authority under section 404(c)(2) of the CSPA to notify the appropriate congressional committees of such waiver and the justification for granting such waiver.

You are hereby authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, September 29, 2015

Presidential Documents

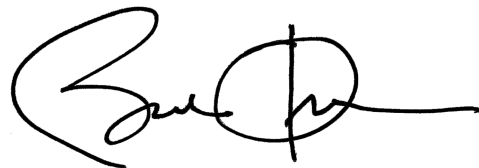
Presidential Determination No. 2015–13 of September 29, 2015

Determination With Respect to the Child Soldiers Prevention Act of 2008

Memorandum for the Secretary of State

Pursuant to section 404 of the Child Soldiers Prevention Act of 2008 (22 U.S.C. 2370c–1) (CSPA), I hereby determine that it is in the national interest of the United States to waive the application of the prohibition in section 404(a) of the CSPA with respect to the Democratic Republic of the Congo, Nigeria, and Somalia; and to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to South Sudan to allow for the provision of International Military Education and Training, and Peacekeeping Operations assistance, and support provided pursuant to section 1208 of the National Defense Authorization Act of Fiscal Year 2014, to the extent such assistance or support would be restricted by the CSPA. I hereby waive such provisions accordingly.

You are hereby authorized and directed to submit this determination to the Congress, along with the accompanying Memorandum of Justification, and to publish the determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, September 29, 2015

Presidential Documents

Presidential Determination No. 2015–14 of September 29, 2015

Presidential Determination on Refugee Admissions for Fiscal Year 2016

Memorandum for the Secretary of State

In accordance with section 207 of the Immigration and Nationality Act (the “Act”) (8 U.S.C. 1157), and after appropriate consultations with the Congress, I hereby make the following determinations and authorize the following actions:

The admission of up to 85,000 refugees to the United States during Fiscal Year (FY) 2016 is justified by humanitarian concerns or is otherwise in the national interest; provided that this number shall be understood as including persons admitted to the United States during FY 2016 with Federal refugee resettlement assistance under the Amerasian immigrant admissions program, as provided below.

The admissions numbers shall be allocated among refugees of special humanitarian concern to the United States in accordance with the following regional allocations; provided that the number of admissions allocated to the East Asia region shall include persons admitted to the United States during FY 2016 with Federal refugee resettlement assistance under section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, as contained in section 101(e) of Public Law 100–202 (Amerasian immigrants and their family members):

Africa	25,000
East Asia	13,000
Europe and Central Asia	4,000
Latin America/Caribbean	3,000
Near East/South Asia	34,000
Unallocated Reserve	6,000

The 6,000 unallocated refugee numbers shall be allocated to regional ceilings, as needed. Upon providing notification to the Judiciary Committees of the Congress, you are hereby authorized to use unallocated admissions in regions where the need for additional admissions arises.

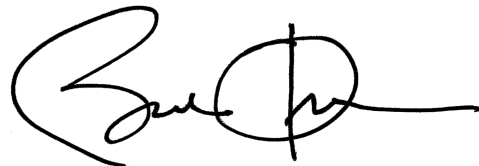
Additionally, upon notification to the Judiciary Committees of the Congress, you are further authorized to transfer unused admissions allocated to a particular region to one or more other regions, if there is a need for greater admissions for the region or regions to which the admissions are being transferred.

Consistent with section 2(b)(2) of the Migration and Refugee Assistance Act of 1962, I hereby determine that assistance to or on behalf of persons applying for admission to the United States as part of the overseas refugee admissions program will contribute to the foreign policy interests of the United States and designate such persons for this purpose. Consistent with section 101(a)(42) of the Act (8 U.S.C. 1101(a)(42)), and after appropriate consultation with the Congress, I also specify that, for FY 2016, the following persons may, if otherwise qualified, be considered refugees for the purpose of admission to the United States within their countries of nationality or habitual residence:

- a. Persons in Cuba
- b. Persons in Eurasia and the Baltics

- c. Persons in Iraq
- d. Persons in Honduras, Guatemala, and El Salvador
- e. In exceptional circumstances, persons identified by a United States Embassy in any location

You are authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, September 29, 2015

Presidential Documents

Presidential Determination No. 2016–01 of October 5, 2015

Presidential Determination With Respect to Foreign Governments' Efforts Regarding Trafficking in Persons

Memorandum for the Secretary of State

Consistent with section 110 of the Trafficking Victims Protection Act of 2000 (the "Act") (22 U.S.C. 7107), I hereby:

Make the determination provided in section 110(d)(1)(A)(i) of the Act, with respect to the Democratic People's Republic of Korea, Equatorial Guinea, Iran, South Sudan, Venezuela, Yemen, and Zimbabwe not to provide certain funding for those countries' governments for Fiscal Year (FY) 2016, until such governments comply with the minimum standards or make significant efforts to bring themselves into compliance, as may be determined by the Secretary of State in a report to the Congress pursuant to section 110(b) of the Act;

Make the determination provided in section 110(d)(1)(A)(ii) of the Act, with respect to Eritrea, Russia, and Syria not to provide certain funding for those countries' governments for FY 2016, until such governments comply with the minimum standards or make significant efforts to bring themselves into compliance, as may be determined by the Secretary of State in a report to the Congress pursuant to section 110(b) of the Act;

Determine, consistent with section 110(d)(4) of the Act, with respect to Algeria, Belarus, Belize, Burundi, the Central African Republic, Comoros, the Gambia, Guinea-Bissau, Kuwait, Libya, Marshall Islands, Mauritania, and Thailand that provision to these countries' governments of all programs, projects, or activities described in sections 110(d)(1)(A)(i)–(ii) and 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Yemen, that a partial waiver to allow assistance and programs described in section 110(d)(1)(A)(i) of the Act, with the exception of International Military Education and Training, Foreign Military Financing, and Excess Defense Articles, would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to South Sudan, that a partial waiver to allow assistance and programs described in section 110(d)(1)(A)(i) of the Act, with the exception of Foreign Military Financing, Foreign Military Sales, and Excess Defense Articles, would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to South Sudan, that a waiver to allow assistance to be provided pursuant to section 1208 of the National Defense Authorization Act for Fiscal Year 2014 (Public Law 113–66), to the extent that such programs would otherwise be restricted by the Act, would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Venezuela, that a partial waiver to allow funding for programs described in section 110(d)(1)(A)(i) of the Act designed to strengthen the democratic

process in Venezuela would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Eritrea, Russia, and Syria, that a partial waiver to allow funding for educational and cultural exchange programs described in section 110(d)(1)(A)(ii) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Equatorial Guinea, that a partial waiver to allow funding described in section 110(d)(1)(A)(i) of the Act to build the capacity of countries to prevent, detect, and respond to infectious diseases; deliver self-help to vulnerable individuals and communities; and support the participation of government employees or officials in young leader exchanges programming would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Equatorial Guinea, South Sudan, Syria, Venezuela, and Yemen, that assistance described in section 110(d)(1)(B) of the Act would promote the purposes of the Act or is otherwise in the national interest of the United States;

Determine, consistent with section 110(d)(4) of the Act, with respect to Zimbabwe, that a partial waiver to continue humanitarian demining initiatives and support programs described in section 110(d)(1)(A)(i) of the Act for assistance for victims of trafficking in persons or to combat such trafficking, and for programs that promote health, disease prevention, good governance, education, leadership, agriculture and food security, poverty reduction, livelihoods, family planning and reproductive health, macroeconomic growth, and biodiversity and wildlife protection, and that would have a significant adverse effect on vulnerable populations if suspended, would promote the purposes of the Act or is otherwise in the national interest of the United States;

And determine, consistent with section 110(d)(4) of the Act, with respect to Zimbabwe, that assistance described in section 110(d)(1)(B) of the Act, which:

(1) is a regional program, project, or activity under which the total benefit to Zimbabwe does not exceed 10 percent of the total value of such program, project, or activity;

(2) has as its primary objective the addressing of basic human needs, as defined by the Department of the Treasury with respect to other, existing legislative mandates concerning U.S. participation in the multilateral development banks;

(3) is complementary to or has similar policy objectives to programs being implemented bilaterally by the United States Government;

(4) has as its primary objective the improvement of Zimbabwe's legal system, including in areas that impact Zimbabwe's ability to investigate and prosecute trafficking cases or otherwise improve implementation of its anti-trafficking policy, regulations, or legislation;

(5) is engaging a government, international organization, or civil society organization, and seeks as its primary objective(s) to: (a) increase efforts to investigate and prosecute trafficking in persons crimes; (b) increase protection for victims of trafficking through better screening, identification, rescue and removal, aftercare (shelter, counseling), training, and reintegration; or (c) expand prevention efforts through education and awareness campaigns highlighting the dangers of trafficking in persons or training and economic empowerment of populations clearly at risk of falling victim to trafficking; or

(6) is targeted macroeconomic assistance from the International Monetary Fund that strengthens the macroeconomic management capacity of

Zimbabwe, would promote the purposes of the Act or is otherwise in the national interest of the United States.

The certification required by section 110(e) of the Act is provided herewith. You are hereby authorized and directed to submit this determination to the Congress, and to publish it in the *Federal Register*.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by a circle and a horizontal line.

THE WHITE HOUSE,
Washington, October 5, 2015

Rules and Regulations

Federal Register

Vol. 80, No. 200

Friday, October 16, 2015

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

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

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

7 CFR Part 635

RIN 0578-AA57

NRCS Procedures for Granting Equitable Relief

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: The Natural Resources Conservation Service (NRCS) issues its final rule implementing the equitable relief authority, and the procedures set forth in section 1613 of the Farm Security and Rural Investment Act of 2002 (the 2002 Act), relating to relief for participants for covered programs administered by NRCS. The relief applies to cases where the program participant took action to his or her detriment based on action or advice from an NRCS employee, and situations where the participant acted in good faith, but failed to fully comply with program requirements.

DATES: This rule is effective October 16, 2015.

FOR FURTHER INFORMATION CONTACT: Paulette Craig, National Equitable Relief Specialist, at (301) 504-1650.

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13563

The Office of Management and Budget (OMB) designated this rule as not significant under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, OMB will not review this final rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601-612) 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. However, this regulation implements section 1613 of the 2002 Act, which is part of Title I of the 2002 Act. Section 1601(c) of the 2002 Act requires NRCS to promulgate regulations or administer Title I without regard to 5 U.S.C. 553. Therefore, NRCS did not prepare a regulatory flexibility analysis for this final rule.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, or the private sector of \$100 million or more in any one year.

This rule contains no Federal mandates, as defined under Title II of UMRA, for State, local, and Tribal governments, or the private sector. Therefore, a statement under section 202 of UMRA is not required.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996, (Pub. L. 104-121). Therefore, NRCS is not required to delay the effective date for 60 days from the date of publication to allow for congressional review. Accordingly, this rule is effective upon publication in the **Federal Register**.

Paperwork Reduction Act

Section 1601(c)(2) of the 2002 Act requires that the implementation of this provision be carried out without regard to the Paperwork Reduction Act, Chapter 35 of Title 44, United States Code. Therefore, NRCS is not reporting recordkeeping or estimated paperwork burden associated with this final rule.

Government Paperwork Elimination Act

NRCS is committed to compliance with the Government Paperwork Elimination Act as well as continued pursuit of providing all services electronically when practicable. This rule requires that a program participant make a written request for equitable relief for a program administered by NRCS. In part, this rule lends itself to electronic requests as submitted by State Conservationists or participants.

Environmental Analysis

NRCS has determined that changes made by this rule fall within a category of actions that are excluded from the requirement to prepare either an environmental assessment or an environmental impact statement. Administrative changes made in this rule fall within a categorical exclusion for policy development relating to routine activities and similar administrative functions (7 CFR 1b.3(a)(1)) and NRCS has identified no extraordinary circumstances that would otherwise require preparation of either.

Civil Rights Impact Analysis

NRCS has determined through a Civil Rights Impact Analysis (CRIA) that the final rule discloses no disproportionately adverse impacts for minorities, women, or persons with disabilities. The CRIA provides responses to the Final rule amendments.

The data presented indicates producers who are members of the protected groups have participated in NRCS conservation programs at parity with other producers. Extrapolating from historical participation data, it is reasonable to conclude that NRCS programs, including procedures for granting equitable relief for ineligibility for these programs, will continue to be administered in a non-discriminatory manner. Outreach and communication strategies are in place to ensure all producers will be provided the same information to allow them to make informed compliance decisions regarding the use of their lands that will affect their participation in U.S. Department of Agriculture (USDA) programs.

The equitable relief procedures apply to all persons equally regardless of their race, color, national origin, gender, sex, or disability status. Therefore, the final rule portends no adverse civil rights implications for women, minorities, or persons with disabilities.

Discussion of the Rule 7 CFR Part 635—Equitable Relief From Ineligibility

Section 635.1 Definitions and Abbreviations

This section amends, adds, or removes a number of defined terms in the rule. Specifically, it adds definitions for “appeal rights,” “equitable relief,” “participant,” and “State.” “Appeal rights” is defined to clarify that a

decision under this rule may be appealed to the National Appeals Division (NAD). “Participant” and “State” are defined consistent with their statutory definitions. The definitions of “covered program” and “State Conservationist” are simplified. The definition of “Natural Resources Conservation Service (NRCS)” is revised to be consistent with the definition used in other NRCS regulations, and clarifies that the term includes programs administered by the agency using the funds, facilities, and authorities of the Commodity Credit Corporation (CCC).

Section 635.2 *Applicability*

The amended rule clarifies the application of subsection (a), and strikes subsections (b) and (c) which are no longer needed.

Section 635.3 *Reliance on Incorrect Actions or Information*

The amended rule makes changes to this section to more closely conform to the language of the statute by enumerating the specific requirements to qualify for relief under this section. These changes do not substantively change the scope of this authority.

Section 635.4 *Failure To Fully Comply*

Section 635.4 of the amended rule makes changes to this section to more closely conform to the language of the statute by enumerating the specific requirements to qualify for relief under this section. These changes provide more flexibility for State Conservationists and participants to request equitable relief, and do not substantively change the scope of this authority.

Section 635.5 *Forms of Relief*

The amended rule makes technical and grammatical changes to this section, and removes references to “loans” since NRCS does not have authority to make loans.

Section 635.6 *Equitable Relief by State Conservationists*

The amended rule restructures and clarifies the existing language of § 635.6. In particular, the revised section explains the limitations on a State Conservationist’s authority in a separate subsection, and amends the description of the State Conservationist’s authority to more closely reflect the statutory language.

Section 635.7 *Procedures for Granting Equitable Relief*

The amended rule strikes the list of covered programs in paragraph (a). The

definition of “covered programs” sufficiently identifies these programs.

The amended rule allows the Chief, State Conservationist, or participant to initiate a request for equitable relief. Under the current rule, only the participant can initiate a request for equitable relief. The State Conservationist cannot initiate a request even if he or she believes the participant qualifies for such relief. For example, an NRCS employee’s misaction or misinformation may impact several different participants, resulting in a number of them being determined ineligible for program benefits. Under the current rule, the participants must request equitable relief from NRCS in order to obtain equitable relief. The State Conservationist cannot initiate an equitable relief request, even if he or she knows that other participants would likely also qualify for equitable relief. Given the potential for treating participants differently, NRCS is amending this procedure to allow the Chief or a State Conservationist to initiate a request for equitable relief for a participant meeting the requirements of this part.

Section 635.7 is also amended to add § 635.7(e) and (f). Paragraph 635.7(e) provides that requests for equitable relief must include any information necessary to determine eligibility under this authority and such other information as required by NRCS to determine whether granting equitable relief is appropriate. This revision reflects that the information needed by the agency to assess equitable relief requests will be provided and updated by applicable policy and procedure at Title 440 of the Conservation Program Manual, Part 509.

Paragraph 635.7(f) provides the participant with appeal rights to the National Appeals Division, pursuant to § 614.9(e) of this chapter, if equitable relief is denied.

List of Subjects in 7 CFR Part 635

Administrative practice and procedure, Agriculture, Conservation programs, Equitable Relief.

Accordingly, for the reasons set forth in the preamble, 7 CFR part 635 is revised to read as follows:

PART 635—EQUITABLE RELIEF FROM INELIGIBILITY

Sec.

- 635.1 Definitions and abbreviations.
- 635.2 Applicability.
- 635.3 Reliance on incorrect actions or information.
- 635.4 Failure to fully comply.
- 635.5 Forms of relief.

635.6 Equitable relief by State Conservationists.

635.7 Procedures for granting equitable relief.

Authority: 7 U.S.C. 7996.

§ 635.1 Definitions and abbreviations.

The following terms apply to this part:

Appeal rights means the right of the participant to appeal a decision to the National Appeals Division (NAD) pursuant to part 614 of this chapter.

Chief means the Chief of the Natural Resources Conservation Service or a person with delegated authority to act for the Chief.

Covered program means a conservation program administered by NRCS.

Equitable relief means an action described in § 635.5 of this part.

Natural Resources Conservation Service (NRCS) means an agency of the U.S. Department of Agriculture which has responsibility for administering covered programs, including those using the funds, facilities, and authorities of the Commodity Credit Corporation (CCC).

OGC means the Office of the General Counsel of the U.S. Department of Agriculture.

Participant means a participant in a covered program.

Secretary means the Secretary of U.S. Department of Agriculture.

State means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

State Conservationist means the NRCS employee authorized to direct and supervise NRCS activities in a State or the State Conservationist’s designee.

§ 635.2 Applicability.

This part applies to all covered programs administered by the Natural Resources Conservation Service, except for the Highly Erodible Land and Wetland Conservation provisions of Title XII, subtitles B and C of the Food Security Act of 1985, as amended, (16 U.S.C. 3811 *et seq.*). Administration of this part shall be under the supervision of the Chief, except that such authority shall not limit the exercise of authority by State Conservationists of the Natural Resources Conservation Service provided in § 635.6 of this part.

§ 635.3 Reliance on incorrect actions or information.

The Chief may grant equitable relief to any participant that NRCS determines is not in compliance with the requirements, terms and conditions of a

covered program, and therefore ineligible for a payment, or other benefit, if the participant—

(a) Acting in good faith, relied on action and advice from an NRCS employee or representative of USDA to their detriment;

(b) Did not know or have sufficient reason to know that the action or advice upon which they relied would be detrimental; and

(c) Did not act in reliance on their own misunderstanding or misinterpretation of the program provisions, notices, or information.

§ 635.4 Failure to fully comply.

The Chief may grant equitable relief to any participant that NRCS determines is not in full compliance with the requirements, terms and conditions of a covered program, and therefore ineligible for a payment, or other benefit, if the participant—

(a) Made a good faith effort to comply fully with the requirements; and

(b) Rendered substantial performance.

§ 635.5 Forms of relief.

(a) The Chief may authorize a participant in a covered program to:

(1) Retain payments or other benefits received under the covered program;

(2) Continue to receive payments and other benefits under the covered program;

(3) Continue to participate, in whole or in part, under any contract executed under the covered program;

(4) Re-enroll all or part of the land covered by the program; and

(5) Receive such other equitable relief as determined to be appropriate.

(b) As a condition of receiving relief under this part, the participant may be required to remedy their failure to meet the program requirement or mitigate its effects.

§ 635.6 Equitable relief by State Conservationists.

(a) *State Conservationists' Authority.* State Conservationists have the authority to grant requests for equitable relief under this section when—

(1) The program matter with respect to which the relief is sought is a program matter in a covered program operated within the authorized jurisdiction of the State Conservationist;

(2) The total amount of relief (including payments and other benefits) that will be provided to the participant under this section during the fiscal year is less than \$20,000;

(3) The total amount of such relief that has been previously provided to the participant using this section in the fiscal year, as calculated in paragraph

(a)(2) of this section, is not more than \$5,000;

(4) The total amount of payments and benefits of any kind for which relief is provided to similarly situated participants by a State Conservationist in a fiscal year, is not more than \$1,000,000.

(b) *Additional limits on authority.* The authority provided under this section does not extend to the administration of:

(1) Payment limitations under part 1400 of this title;

(2) Payment limitations under a conservation program administered by the Secretary; or

(3) The highly erodible land and wetland conservation requirements under subtitles B or C of Title XII of the Food Security Act of 1985 (16 U.S.C. 3811 *et seq.*).

(c) *Concurrence by the Office of the General Counsel.* Relief shall only be made under this part after consultation with, and concurrence by, the Office of General Counsel.

(d) *Secretary's reversal authority.* A decision made under this part by the State Conservationist may be reversed only by the Secretary, who may not delegate that authority.

(e) *Relation to other authorities.* The authority provided under this section is in addition to any other applicable authority that may allow relief.

§ 635.7 Procedures for granting equitable relief.

(a) The Chief or State Conservationist may initiate a request for equitable relief for a participant that meets the requirement of this part.

(b) Participants may request equitable relief from the Chief or the State Conservationist as provided in §§ 635.3 and 635.4 of this part.

(c) Only a participant directly affected by the non-compliance with the covered program requirements is eligible for equitable relief under this part.

(d) Requests by a participant for equitable relief must be made in writing, no later than 30 calendar days from the date of receipt of the notification of non-compliance with the requirements of the covered conservation program.

(e) Requests for equitable relief must include any information necessary to determine eligibility under this part and such other information as required by NRCS to determine whether granting equitable relief is appropriate. Information needed by the agency to assess equitable relief requests will be provided and updated by applicable policy and procedure.

(f) If equitable relief is denied by the Chief or the State Conservationist, the participant will be provided with

written notice of appeal rights to the National Appeals Division, pursuant to 7 CFR part 614.

Signed this 7th day of October, 2015, in Washington, DC.

Leonard Jordan,

Associate Chief for Conservation, Natural Resources Conservation Service.

[FR Doc. 2015-26309 Filed 10-15-15; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE-2013-BT-TP-0009]

RIN 1904-AC97

Energy Conservation Program for Consumer Products: Test Procedures for Clothes Washers; Correcting Amendments

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule; correcting amendments.

SUMMARY: On August 5, 2015, the U.S. Department of Energy (DOE) published a final rule amending the test procedures for clothes washers. This correction addresses several cross-reference numbering errors, in which the cross-references were inadvertently not updated to reflect the revised section numbering resulting from the final rule amendments. In addition, this correction republishes several amendments from the final rule that could not be incorporated into the Code of Federal Regulations (CFR) due to inaccurate amendatory instructions, and clarifies several of the amendatory instructions in the final rule to remove certain sections of the test procedures. Furthermore, this correction reinstates three sections of the clothes washer test procedure that were inadvertently removed from the CFR starting with the 2013 annual edition. Neither the errors nor the corrections in this document affect the substance of the rulemaking or any of the conclusions reached in support of either of these final rules.

DATES: *Effective Date:* October 16, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Berringer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-0371. Email: Bryan.Berringer@ee.doe.gov.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel,

GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-9507. Email: *Eric.Stas@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: DOE published a final rule in the **Federal Register** on August 5, 2015 (the “August 2015 final rule”), amending the test procedures for clothes washers. 80 FR 46729. In the rule, several section number cross-references were inadvertently not updated to reflect the revised section numbering resulting from the final rule amendments. These errors apply to both Appendix J1 and Appendix J2 to subpart B of 10 CFR part 430. Table 1 summarizes the affected sections and the associated corrections.

TABLE 1—CORRECTIONS TO SECTION NUMBER CROSS-REFERENCES

Appendix J1	
Section 2.7	Existing reference to section 3.1.5 updated to 3.1.6.
Section 4.2.3 ..	
Section 4.4	
Section 3.6	Existing reference to section 1.18 updated to 1.20.
Section 3.7.1 ..	Existing reference to section 3.5.2.3 updated to 3.5.3.
Section 3.7.2 ..	
Appendix J2	
Section 3.8.2.6	Existing reference to “section 6.3 of this appendix” updated to “section 7 of appendix J3 to 10 CFR part 430, subpart B.”
Section 3.8.3.2	Existing reference to “section 6.2.1 of this appendix” updated to “section 6.1 of appendix J3 to 10 CFR part 430, subpart B.”
Section 3.8.3.4	
Section 4.2.4 ..	Existing reference to section 3.7 updated to 3.6.
Section 4.2.5 ..	Existing reference to section 3.6 updated to 3.7.
Section 4.2.12	Existing reference to section 3.1.6 updated to 3.1.7.
Section 4.2.13	
Section 4.5	
Section 4.6	

In addition, this final rule republishes the amendments to sections 2.6.5.1 and 2.6.5.2. It also clarifies that sections 2.6.5.3 (including its subsections), 2.6.5.4, 2.6.6.1, 2.6.6.2, 2.6.7.1, and 2.6.7.2 of Appendix J1 are to be removed.

Finally, in a test procedure final rule published on March 7, 2012 (the “March 2012 final rule”), DOE amended section 3.6 of Appendix J1 and intended for sections 3.6.1 through 3.6.3 to remain unchanged. 77 FR 13888. In the January 1, 2013 version of the CFR, sections 3.6.1 through 3.6.3 of Appendix J1 were inadvertently removed. Section 3.6 requires measuring water and electrical energy consumption for the

Cold Wash temperature selection using the water fill levels and test load sizes specified in sections 3.6.1 through 3.6.3. As was the case prior to the inadvertent deletion and as reinstated, sections 3.6.1 through 3.6.3 provide these specifications and also define the variables associated with each measurement. This final rule correction reinstates these sections as they appeared in the January 1, 2012 version of the CFR, except that the word “adaptive” in section 3.6.3 is changed to “automatic,” as described in the August 2015 final rule.

Procedural Issues and Regulatory Review

The regulatory reviews conducted for this rulemaking are those set forth in the March 2012 final rule and August 2015 final rule that originally codified the respective amendments to DOE’s test procedures for clothes washers. The amendments in the March 2012 final rule became effective April 6, 2012, and the amendments in the August 2015 final rule became effective September 4, 2015.

Pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b), DOE has determined that notice and prior opportunity for comment on this rule are unnecessary and contrary to the public interest. Neither the errors nor the corrections in this document affect the substance of the rulemakings or any of the conclusions reached in support of either of these final rules. For these reasons, DOE has also determined that there is good cause to waive the 30-day delay in effective date.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on October 5, 2015.

Kathleen B. Hogan,
Deputy Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, part 430 of title 10 of the Code of Federal Regulations is corrected by making the following correcting amendments:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291-6309; 28 U.S.C. 2461 note.

- 2. Appendix J1 to subpart B of part 430 is amended by:
- a. Revising sections 2.6.5.1 and 2.6.5.2;
- b. Removing sections 2.6.5.3, 2.6.5.3.1 through 2.6.5.3.6, 2.6.5.4, 2.6.6.1, 2.6.6.2, 2.6.7.1, and 2.6.7.2;
- c. Revising sections 2.7, 3.6, 3.7.1, 3.7.2, 4.2.3, and 4.4; and
- d. Adding sections 3.6.1, 3.6.2, and 3.6.3.

The revisions and additions read as follows:

Appendix J1 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Automatic and Semi-Automatic Clothes Washers

* * * * *

2.6.5.1 Using the coefficients A and B calculated in Appendix J3 to 10 CFR part 430, subpart B:

$$RMC_{corr} = A \times RMC + B$$

2.6.5.2 Substitute RMC_{corr} values in calculations in section 3.8 of this appendix.

* * * * *

2.7 *Test Load Sizes.* Maximum, minimum, and, when required, average test load sizes shall be determined using Table 5.1 of this appendix and the clothes container capacity as measured in sections 3.1.1 through 3.1.6 of this appendix. Test loads shall consist of energy test cloths, except that adjustments to the test loads to achieve proper weight can be made by the use of energy stuffer cloths with no more than 5 stuffer cloths per load.

* * * * *

3.6 “Cold Wash” (*Minimum Wash Temperature Selection*). Water and electrical energy consumption shall be measured for each water fill level or test load size as specified in sections 3.6.1 through 3.6.3 of this appendix for the coldest wash temperature selection available. For a clothes washer that offers two or more wash temperature settings labeled as cold, such as “Cold” and “Tap Cold,” the setting with the minimum wash temperature shall be considered the cold wash. If any of the other cold wash temperature settings add hot water to raise the wash temperature above the cold water supply temperature, as defined in section 2.3 of this appendix, those setting(s) shall be considered warm wash setting(s), as defined in section 1.20 of this appendix. If none of the cold wash temperature settings add hot water for any of the water fill levels or test load sizes required for the energy test cycle, the wash temperature setting labeled as “Cold” shall be considered the cold wash, and the other wash temperature setting(s) labeled as cold shall not be required for testing.

3.6.1 *Maximum test load and water fill.* Hot water consumption (Hc_x), cold water consumption (Cc_x), and electrical energy consumption (Ec_x) shall be measured for a cold wash/cold rinse energy test cycle, with the controls set for the maximum water fill level. The maximum test load size is to be used and shall be determined per Table 5.1 of this appendix.

3.6.2 *Minimum test load and water fill.* Hot water consumption (Hc_n), cold water

consumption (C_{c,n}), and electrical energy consumption (E_{c,n}) shall be measured for a cold wash/cold rinse energy test cycle, with the controls set for the minimum water fill level. The minimum test load size is to be used and shall be determined per Table 5.1 of this appendix.

3.6.3 *Average test load and water fill.* For clothes washers with an automatic water fill control system, measure the values for hot water consumption (H_{c,a}), cold water consumption (C_{c,a}), and electrical energy consumption (E_{c,a}) for a cold wash/cold rinse energy test cycle, with an average test load size as determined per Table 5.1 of this appendix.

3.7.1 For the rinse only, measure the amount of hot water consumed by the clothes washer including all deep and spray rinses, for the maximum (R_x), minimum (R_n), and, if required by section 3.5.3 of this appendix, average (R_a) test load sizes or water fill levels.

3.7.2 Measure the amount of electrical energy consumed by the clothes washer to heat the rinse water only, including all deep and spray rinses, for the maximum (E_{R,x}), minimum (E_{R,n}), and, if required by section 3.5.3 of this appendix, average (E_{R,a}) test load sizes or water fill levels.

4.2.3 *Water factor.* Calculate the water factor, WF, expressed in gallons per cycle per cubic foot (or liters per cycle per liter), as:

$$WF = Q_T / C$$

where:

Q_T = As defined in section 4.2.2 of this appendix.

C = As defined in section 3.1.6 of this appendix.

4.4 *Modified energy factor.* Calculate the modified energy factor, MEF, expressed in cubic feet per kilowatt-hour per cycle (or liters per kilowatt-hour per cycle) and defined as:

$$MEF = C / (E_{TE} + D_E)$$

where:

C = As defined in section 3.1.6 of this appendix.

E_{TE} = As defined in section 4.1.7 of this appendix.

D_E = As defined in section 4.3 of this appendix.

■ 3. Appendix J2 to subpart B of part 430 is amended by revising sections 3.8.2.6, 3.8.3.2, 3.8.3.4, 4.2.4, 4.2.5, 4.2.12, 4.2.13, 4.5, and 4.6 to read as follows:

Appendix J2 to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Automatic and Semi-Automatic Clothes Washers

3.8.2.6 Apply the RMC correction curve described in section 7 of appendix J3 to this subpart to calculate the corrected remaining moisture content, RMC_{corr}, expressed as a percentage as follows:

$$RMC_{corr} = (A \times RMC_x + B) \times 100\%$$

where:

A and B are the coefficients of the RMC correction curve as defined in section 6.1 of appendix J3 to this subpart.

RMC_x = As defined in section 3.8.2.5 of this appendix.

3.8.3.2 Apply the RMC correction curve described in section 7 of appendix J3 to this subpart to calculate the corrected remaining moisture content for Cold Wash/Cold Rinse, RMC_{COLD,corr}, expressed as a percentage, as follows:

$$RMC_{COLD,corr} = (A \times RMC_{COLD} + B) \times 100\%$$

where:

A and B are the coefficients of the RMC correction curve as defined in section 6.1 of appendix J3 to this subpart.

RMC_{COLD} = As defined in section 3.8.3.1 of this appendix.

3.8.3.4 Apply the RMC correction curve described in section 7 of appendix J3 to this subpart to calculate the corrected remaining moisture content for Warm Wash/Warm Rinse, RMC_{WARM,corr}, expressed as a percentage, as follows:

$$RMC_{WARM,corr} = (A \times RMC_{WARM} + B) \times 100\%$$

where:

A and B are the coefficients of the RMC correction curve as defined in section 6.1 of appendix J3 to this subpart.

RMC_{WARM} = As defined in section 3.8.3.3 of this appendix.

4.2.4 *Per-cycle water consumption for Warm Wash/Warm Rinse.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the Warm Wash/Warm Rinse cycle and defined as:

$$Q_{WW,max} = [H_{ww,x} + C_{ww,x}]$$

$$Q_{WW,avg} = [H_{ww,a} + C_{ww,a}]$$

$$Q_{WW,min} = [H_{ww,n} + C_{ww,n}]$$

where:

H_{ww,x}, C_{ww,x}, H_{ww,a}, C_{ww,a}, H_{ww,n}, and C_{ww,n} are defined in section 3.6 of this appendix.

4.2.5 *Per-cycle water consumption for Cold Wash/Cold Rinse.* Calculate the maximum, average, and minimum total water consumption, expressed in gallons per cycle (or liters per cycle), for the Cold Wash/Cold Rinse cycle and defined as:

$$Q_{C,max} = [H_{c,x} + C_{c,x}]$$

$$Q_{C,avg} = [H_{c,a} + C_{c,a}]$$

$$Q_{C,min} = [H_{c,n} + C_{c,n}]$$

where:

H_{c,x}, C_{c,x}, H_{c,a}, C_{c,a}, H_{c,n}, and C_{c,n} are defined in section 3.7 of this appendix.

4.2.12 *Water factor.* Calculate the water factor, WF, expressed in gallons per cycle per cubic foot (or liters per cycle per liter), as:

$$WF = Q_{CT} / C$$

where:

Q_{CT} = As defined in section 4.2.10 of this appendix.

C = As defined in section 3.1.7 of this appendix.

4.2.13 *Integrated water factor.* Calculate the integrated water factor, IWF, expressed in gallons per cycle per cubic foot (or liters per cycle per liter), as:

$$IWF = Q_T / C$$

where:

Q_T = As defined in section 4.2.11 of this appendix.

C = As defined in section 3.1.7 of this appendix.

4.5 *Modified energy factor.* Calculate the modified energy factor, MEF, expressed in cubic feet per kilowatt-hour per cycle (or liters per kilowatt-hour per cycle) and defined as:

$$MEF = C / (E_{TE} + D_E)$$

where:

C = As defined in section 3.1.7 of this appendix.

E_{TE} = As defined in section 4.1.7 of this appendix.

D_E = As defined in section 4.3 of this appendix.

4.6 *Integrated modified energy factor.* Calculate the integrated modified energy factor, IMEF, expressed in cubic feet per kilowatt-hour per cycle (or liters per kilowatt-hour per cycle) and defined as:

$$IMEF = C / (E_{TE} + D_E + E_{TLP})$$

where:

C = As defined in section 3.1.7 of this appendix.

E_{TE} = As defined in section 4.1.7 of this appendix.

D_E = As defined in section 4.3 of this appendix.

E_{TLP} = As defined in section 4.4 of this appendix.

[FR Doc. 2015-25963 Filed 10-15-15; 8:45 am]

BILLING CODE 6450-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 352 and 361

RIN 3064-AE35

Nondiscrimination on the Basis of Disability Minority and Women Outreach Program Contracting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: The FDIC is updating its regulations, Nondiscrimination on the Basis of Disability, and Minority and Women Outreach Program Contracting, to reflect a name change from the Agency's Office of Diversity and Economic Opportunity (ODEO) to the Office of Minority and Women Inclusion (OMWI).

DATES: This final rule will become effective on October 16, 2015.

FOR FURTHER INFORMATION CONTACT:

Melodee Brooks, Senior Deputy Director, Office of Minority and Women Inclusion, (703) 562-6090; or Robert Lee, Counsel, Legal Division, (703) 562-2020, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429-0002.

SUPPLEMENTARY INFORMATION:**I. Background**

Following a recent review, the FDIC is updating 12 CFR parts 352 and 361 to reflect a name change from the FDIC Office of Diversity and Economic Opportunity to the FDIC Office of Minority and Women Inclusion.

Part 352 is the FDIC's regulation on nondiscrimination on the basis of disability and is intended to implement sections 504 and 508 of the Rehabilitation Act of 1973, as amended. Section 504 prohibits discrimination on the basis of disability in programs and activities conducted by a federal executive agency. Section 508 requires federal agencies to utilize electronic and information technology that is designed to allow individuals with disabilities access that is comparable to the access of those who are not disabled, unless such agency would incur an undue burden. Subsections 352.9(b) and 352.10 set forth information that is no longer accurate, as the Office of Diversity and Economic Opportunity's responsibilities and employees were transferred to the Office of Minority and Women Inclusion, a new office established by the FDIC Board of Directors pursuant to Section 342 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Act). Section 342 of the Act is codified at 12 U.S.C. 5452. The remaining contact information for OMWI remains the same as that of the predecessor office—3501 N. Fairfax Drive, Arlington, VA 22226; (877) 275-3342 or (703) 562-2473 (TTY).

Part 361 established in regulatory form the FDIC's Minority and Woman Outreach Program (MWOP) to ensure that minority- and women-owned businesses (MWOBs) are given the opportunity to participate fully in all contracts entered into by the FDIC as it is the FDIC's policy that minorities and women, and businesses owned by them have the maximum practicable opportunity to participate in contracts awarded by the FDIC. Subsections 361.5 and 361.6(a) set forth information that is no longer accurate, as the Office of Diversity and Economic Opportunity's responsibilities and employees have been transferred to the Office of Minority and Women Inclusion.

II. Final Rule

The final rule for parts 352 and 361 updates the name of the FDIC Office of Diversity and Economic Opportunity (ODEO) to the FDIC Office of Minority and Women Inclusion (OMWI). The amendments are procedural and non-substantive in nature, and would update the regulations to be consistent with the FDIC's practices and procedures. The revisions to each of the sections cited below in the List of Subjects simply reflect the change in office name.

III. Exemption From Public Notice and Comment

Section 553 of the Administrative Procedure Act (APA)(5 U.S.C. 553) sets forth requirements for providing the general public notice of, and the opportunity to comment on, proposed agency rules. However, unless notice or hearing is required by statute, those requirements do not apply:

(A) To interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice; or
(B) When the agency for good cause finds (and incorporates the findings and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b).

The FDIC is updating parts 352 and 361 to reflect a name change from the FDIC Office of Diversity and Economic Opportunity to the FDIC Office of Minority and Women Inclusion. Since the changes relate to agency organization, procedure, or practice, and because the FDIC has determined for good cause that public notice and comment are unnecessary, the rules are being published in final form without public notice and comment.

IV. Effective Dates

Section 553 of the APA provides that a regulation shall not be made effective less than 30 days after its publication in the **Federal Register** except, among other things, upon a finding of "good cause" by the agency. (5 U.S.C. 553(d)). The FDIC finds that there is good cause to make the amendments to parts 352 and 361 effective immediately upon publication in the **Federal Register** because the name change from the Office of Diversity and Economic Opportunity (ODEO) to the Office of Minority and Women Inclusion (OMWI) is procedural and non-substantive.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) does not apply to a rulemaking where a general notice of proposed rulemaking is not required. (5

U.S.C. 603 and 604). As noted previously, the FDIC has determined that it is unnecessary to publish a notice of proposed rulemaking for the final rule amending part 352. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply to this rulemaking for parts 352 and 361.

VI. The Paperwork Reduction Act

The final rule for parts 352 and 361 does not contain any requirements for the collection of information pursuant to the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*).

VII. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the final rule for parts 352 and 361 will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Pub. L. 105-277, 112 Stat. 2681).

VIII. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget has determined that the final rule for parts 352 and 361 is not a "major rule" within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)(Title II, Pub. L. 104-121). As required by SBREFA, the FDIC will file appropriate reports with Congress and the Government Accountability Office so that the final rule for parts 352 or 361 may be reviewed.

List of Subjects*12 CFR Part 352*

Nondiscrimination on the basis of disability, Access to electronic and information technology, Employment, Communications.

12 CFR Part 361

Minority and Women Outreach Program Contracting.

Authority and Issuance

For the reason set forth in the preamble, parts 352 and 361 of Chapter III of title 12 of the Code of Federal Regulations are amended as follows:

PART 352—NONDISCRIMINATION ON THE BASIS OF DISABILITY

■ 1. The authority citation for part 352 continues to read as follows:

Authority: 12 U.S.C. 1819(a), 29 U.S.C. 794d.

§ 352.9 [Amended]

■ 2. Amend § 352.9(b) by removing the term “Office of Diversity and Economic Opportunity (ODEO)” and adding in its place “Office of Minority and Women Inclusion (OMWI).”

§ 352.10 [Amended]

■ 3. Amend § 352.10:

■ a. In paragraph (c) by removing the term “Office of Diversity and Economic Opportunity” and adding in its place “Office of Minority and Women Inclusion” wherever it occurs and by removing the term “ODEO” and adding in its place “OMWI” wherever it occurs; and

■ b. In paragraphs (e) introductory text, (g), (h), and (i) by removing the term “ODEO” and adding in its place “OMWI” wherever it occurs.

PART 361—MINORITY AND WOMEN OUTREACH PROGRAM CONTRACTING

■ 4. The authority citation for part 361 continues to read as follows:

Authority: 12 U.S.C. 1833e.

§ 361.5 [Amended]

■ 9. Amend § 361.5, in paragraph (a), by removing the term “Office of Diversity and Economic Opportunity (ODEO)” and adding in its place “Office of Minority and Women Inclusion (OMWI)” and in paragraphs (a) and (b), by removing the term “ODEO” and adding in its place “OMWI.”

§ 361.6 [Amended]

■ 10. Revise § 361.6(a) by removing the term “ODEO” and adding in its place “OMWI” wherever it occurs.

Dated this 13th day of October, 2015.
Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–26391 Filed 10–15–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–0252; Airspace Docket No. 15–AEA–1]

Amendment of Class E Airspace; Ashland, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E Airspace at Ashland, VA as new Standard Instrument Approach Procedures have been developed at Hanover County Municipal Airport. This action enhances the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport. This action also updates the geographic coordinates of the airport.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at <http://www.faa.gov/airtraffic/publications/>.

For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code.

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. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Hanover County Municipal Airport, Ashland, VA.

History

On March 9, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E airspace extending upward from 700 feet above the surface at Hanover County Municipal Airport, Ashland, VA. (80 FR 12357). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E airspace extending upward from 700 feet above the surface within a 7-mile radius of Hanover County Municipal Airport, Ashland, VA, providing the controlled airspace required to support the new standard instrument approach procedures for IFR operations at the airport. The geographic coordinates of the airport are adjusted to be in concert with the FAA’s aeronautical database.

Class E airspace designations are published in Paragraph 6005 of FAA

Order 7400.9YZ, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71 —DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z,

Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth

* * * * *

AEA VA E5 Ashland, VA [Amended]

Hanover County Municipal Airport, VA
(Lat. 37°42'32" N., long. 77°26'12" W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Hanover County Municipal Airport.

Issued in College Park, Georgia, on October 2, 2015.

Gerald E. Lynch,

*Acting Manager, Operations Support Group,
Eastern Service Center, Air Traffic
Organization.*

[FR Doc. 2015–25901 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

**[Docket No. FAA–2014–0037; Airspace
Docket No. 14–ANE–3]**

Establishment of Class E Airspace; Newport, NH

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E Airspace at Newport, NH, to accommodate new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAPs) serving Parlin Field Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at <http://www.faa.gov/airtraffic/publications/>. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, 20591;

telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Parlin Field Airport, Newport, NH.

History

On August 14, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E airspace extending upward from 700 feet above the surface at Parlin Field Airport, Newport, NH, (80 FR 48766). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and

Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 12.1-mile radius of Parlin Field Airport, Newport, NH, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for Parlin Field Airport.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71 —DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 feet or More Above the Surface of the Earth.

* * * * *

ANE NH E5 Newport, NH [New]

Parlin Field Airport, NH
(Lat. 43°23'14" N., long. 72°11'16" W.)

That airspace extending upward from 700 feet above the surface within a 12.1-mile radius of Parlin Field Airport.

Issued in College Park, Georgia, on October 2, 2015.

Gerald E. Lynch,

*Acting Manager, Operations Support Group,
Eastern Service Center, Air Traffic
Organization.*

[FR Doc. 2015–25900 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–1136; Airspace
Docket No. 15–ANM–12]

Amendment of Class D and Class E Airspace, Revocation of Class E Airspace; Mountain Home, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface, and removes Class E surface area airspace designated

as an extension at Mountain Home AFB, Mountain Home, ID. The FAA found it necessary to amend the airspace area by increasing the Class D airspace and reducing the Class E airspace extending upward from 700 feet above the surface for the safety and management of Instrument Flight Rules (IFR) operations for arriving and departing aircraft at the airport and to change from navigation aids to geographic coordinate references in the legal description. This action updates the geographic coordinates of Mountain Home Municipal Airport, Mountain Home, ID.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC, 29591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA, 98057; telephone (425) 203–4500.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use

of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Mountain Home AFB, ID.

History

On July 28, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to modify Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface, and remove Class E surface area airspace designated as an extension at Mountain Home AFB, Mountain Home, ID, (80 FR 44896). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received from Mr. Ted Thompson expressing concern about the reduction of Class E airspace to the west of Mountain Home Municipal airport if an instrument approach is established from the west. In accordance with FAA Joint Order 7400.2K, airspace is established based upon existing procedures. Any changes to airspace that would be required by the development of a new instrument procedure would be addressed at that time. Subsequent to publication, the FAA found slight changes were necessary in the geographic coordinates noted in the legal description of the Class E airspace extending upward from 1,200 feet above surface.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class D airspace, Class E surface area airspace, Class E airspace

extending upward from 700 feet above the surface, and removes Class E surface area airspace as an extension at Mountain Home AFB, Mountain Home, ID. After a review, the FAA found an increase of the Class D airspace necessary to protect instrument arrival procedures at the airport. Class D airspace is extended upward from the surface to and including 5,500 feet within a 5-mile radius of Mountain Home AFB, extending to 6.5 miles to the southeast and northwest of the airport. Class E surface area airspace extends upward from the surface within a 5-mile radius of Mountain Home AFB, extending to 6.5 miles to the southeast and northwest of the airport. Class E airspace extending upward from 700 feet above the surface is modified to within a 7.7-mile radius northeast of Mountain Home AFB, extending to 12.4 miles to the northeast, and 17.7 miles to the east. The lateral boundary for that Class E airspace extending from 1,200 feet above the surface is defined utilizing latitude and longitude reference points instead of Federal airway reference, and does not change the lateral boundaries or operating requirements of the 1,200 foot airspace. This action also updates the geographic coordinates of Mountain Home Municipal Airport, Mountain Home, ID.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, “Environmental Impacts: Policies and Procedures,” paragraph 311a. This airspace action is not expected to cause any potentially

significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 5000 Class D airspace
* * * * *

ANM ID D Mountain Home, ID [Modified]

Mountain Home AFB, ID
(Lat. 43°02'37" N., long. 115°52'21" W.)

That airspace extending upward from the surface to and including 5,500 feet MSL within a 5-mile radius of the Mountain Home AFB and within 2 miles each side of the 135° bearing from the airport extending from the 5-mile radius to 6.5 miles southeast of the airport, and within 2 miles each side of the 315° bearing from the airport extending from the 5-mile radius to 6.5 miles northwest of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E Airspace Designated as Surface Areas
* * * * *

ANM ID E2 Mountain Home, ID [Modified]

Mountain Home AFB, ID
(Lat. 43°02'37" N., long. 115°52'21" W.)

That airspace extending upward from the surface within a 5-mile radius of the Mountain Home AFB, and within 2 miles each side of the 135° bearing from the airport extending from the 5-mile radius to 6.5 miles southeast of the airport, and within 2 miles each side of the 315° bearing from the airport extending from the 5-mile radius to 6.5 miles northwest of the airport.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ANM ID E4 Mountain Home, ID [Removed]

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ANM ID E5 Mountain Home, ID [Modified]

Mountain Home AFB, ID

(Lat. 43°02'37" N., long. 115°52'21" W.)

Mountain Home Municipal Airport

(Lat. 43°07'54" N., long. 115°43'50" W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 43°06'48" N., long. 115°28'39" W.; to lat. 43°02'06" N., long. 115°31'12" W.; to lat. 43°03'25" N., long. 115°36'21" W.; to lat. 42°54'24" N., long. 115°48'41" W.; to lat. 42°54'24" N., long. 115°56'47" W.; to lat. 43°00'12" N., long. 116°04'42" W.; to lat. 43°06'51" N., long. 116°01'24" W.; to lat. 43°09'22" N., long. 115°57'57" W.; to lat. 43°12'54" N., long. 115°42'51" W., thence to point of beginning, that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 43°33'06" N., long. 116°11'32" W.; to lat. 42°48'43" N., long. 115°00'21" W.; to lat. 42°23'58" N., long. 115°00'21" W.; to lat. 42°23'58" N., long. 115°18'28" W.; thence clockwise along the 46.0-mile radius of Mountain Home AFB to lat. 43°09'17" N., long. 116°54'28" W.; thence to point of beginning.

Issued in Seattle, Washington, on October 1, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015-25991 Filed 10-15-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2014-0967; Airspace Docket No. 14-ASO-19]

Amendment of Class E Airspace; Ponce, PR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E Airspace at Ponce, PR, as the PONCE VHF Omni-Directional Radio Range Tactical Air Navigation Aid, (VORTAC) has been decommissioned, requiring airspace redesign at Mercedita Airport. This action enhances the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at <http://www.faa.gov/airtraffic/publications/>. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC, 20591; telephone: 202-267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Mercedita Airport, Ponce, PR.

History

On July 16, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E surface area airspace at Mercedita Airport, Ponce, PR, due to the decommissioning of the Ponce VORTAC (80 FR 42068). Interested parties were

invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6002 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 amends Class E surface area airspace at Mercedita Airport, Ponce, PR.

Airspace reconfiguration to within a 4.1-mile radius of the airport is necessary due to the decommissioning of the Ponce VORTAC and cancellation of the VOR approach, and for continued safety and management of IFR operations at the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion

under the National Environmental Policy Act in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71:

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71 —DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas

* * * * *

ASO PR E2 Ponce, PR [Amended]

Mercedita Airport, PR

(Lat. 18°00'30" N., long. 66°33'47" W.)

Within a 4.1-mile radius of Mercedita Airport. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in College Park, Georgia, on October 2, 2015.

Gerald E. Lynch,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2015–25853 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–2270; Airspace Docket No. 12–AWP–11]

Establishment of Class E Airspace, Cottonwood, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Cottonwood Airport, Cottonwood, AZ, to accommodate new Standard Instrument Approach Procedures (SIAP) at the airport. The FAA found establishment of controlled airspace necessary for the safety and management of Instrument Flight Rules (IFR) operations.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA, 98057; telephone (425) 203–4500.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Cottonwood, AZ.

History

On August 5, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E airspace extending upward from 700 feet above the surface at Cottonwood Airport, Cottonwood, AZ, (80 FR 46525). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designation is published in paragraph 6005, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface at Cottonwood Airport, Cottonwood, AZ. New standard instrument approach procedures have been developed for IFR operations at the airport. The Class E airspace is established to within a 4-mile radius of Cottonwood Airport, with a segment extending from the 4-mile radius to 15 miles southeast of the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which

frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

AWP AZ E5 Cottonwood, AZ [New]
Cottonwood Airport, AZ

(Lat. 34°43'48" N., long. 112°02'07" W.)

That airspace extending upward from 700 feet above the surface within a 4-mile radius of Cottonwood Airport excluding that airspace southwest of a line beginning where the 299° bearing from the airport intersects the 4-mile radius to a point where the 181° bearing from the airport intersects the 4-mile radius; and that airspace 1.8 miles southwest and 1.2 miles northeast of the 150° bearing from the 4-mile radius to 15 miles southeast of the airport.

Issued in Seattle, Washington, on October 1, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–26002 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–1833; Airspace Docket No. 15–ASW–7]

Establishment of Class E Airspace; Marshall, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Marshall, AR. Controlled airspace is necessary to accommodate new Standard Instrument Approach Procedures at Searcy County Airport. This action enhances the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at http://www.faa.gov/air_traffic/publications. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC, 29591; telephone: 202–267–8783. The order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to <http://www.archives.gov/>

federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone: 817–222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Searcy County Airport, Marshall, AR

History

On August 13, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E airspace extending upward from 700 feet above the surface at Searcy County Airport, Marshall, AR, copied incorrectly as Concordia Parish Airport, (80 FR 48470). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists

Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14, Code of Federal Regulations (14 CFR), Part 71 by establishing Class E airspace extending upward from 700 feet above the surface within an 11.2-mile radius of Searcy County Airport, Marshall, AR, to accommodate new Standard Instrument Approach Procedures for IFR operations at the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW AR E5 Marshall, AR [New]

Searcy County Airport, AR
(Lat. 35°53'55" N., long. 092°39'23" W.)

That airspace extending upward from 700 feet above the surface within a 11.2-mile radius of Searcy County Airport.

Issued in Fort Worth, TX, on October 7, 2015.

Robert W. Beck,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2015–26095 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31041; Amdt. No. 3664]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 16, 2015. The compliance date for each SIAP, associated Takeoff Minimums,

and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 16, 2015.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE., West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further,

airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFRs, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures

(TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore— (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on September 25, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [AMENDED]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC Date	State	City	Airport	FDC Number	FDC Date	Subject
12–Nov–15	IL	Champaign/Urbana	University Of Illinois-Willard.	5/0256	09/17/15	RADAR 1, Amdt 6B.
12–Nov–15	TX	Fredericksburg	Gillespie County	5/0259	09/17/15	RNAV (GPS) RWY 32, Amdt 1B.
12–Nov–15	KS	Atchison	Amelia Earhart	5/0276	09/17/15	VOR/DME RNAV OR GPS RWY 16, Amdt 4A.
12–Nov–15	KS	Atchison	Amelia Earhart	5/0277	09/17/15	VOR/DME RWY 16, Orig-A.
12–Nov–15	MI	Traverse City	Cherry Capital	5/0652	09/08/15	NDB RWY 28, Amdt 11.
12–Nov–15	TX	Harlingen	Valley Intl	5/0916	09/08/15	VOR/DME RWY 17L, Orig.
12–Nov–15	MI	Holland	West Michigan Rgnl ...	5/1847	09/17/15	RNAV (GPS) RWY 8, Amdt 2B.
12–Nov–15	WI	Middleton	Middleton Muni-Morey Field.	5/1853	09/17/15	VOR RWY 10, Amdt 1A.
12–Nov–15	WI	Prairie Du Chien	Prairie Du Chien Muni	5/1859	09/17/15	RNAV (GPS) RWY 14, Orig-B.
12–Nov–15	AL	Andalusia/Opp	South Alabama Rgnl At Bill Benton Field.	5/1900	09/17/15	RNAV (GPS) RWY 29, Amdt 2A.
12–Nov–15	AL	Andalusia/Opp	South Alabama Rgnl At Bill Benton Field.	5/1901	09/17/15	RNAV (GPS) RWY 11, Amdt 2A.
12–Nov–15	KS	Garden City	Garden City Rgnl	5/2041	09/17/15	VOR/DME RWY 12, Orig-A.
12–Nov–15	KS	Garden City	Garden City Rgnl	5/2043	09/17/15	VOR RWY 17, Amdt 11.
12–Nov–15	KS	Garden City	Garden City Rgnl	5/2045	09/17/15	VOR/DME RWY 17, Amdt 2.
12–Nov–15	KS	Garden City	Garden City Rgnl	5/2047	09/17/15	VOR/DME RWY 30, Amdt 1.
12–Nov–15	ME	Waterville	Waterville Robert La-fleur.	5/2143	09/17/15	RNAV (GPS) RWY 5, Amdt 1.

AIRAC Date	State	City	Airport	FDC Number	FDC Date	Subject
12–Nov–15	ME	Waterville	Waterville Robert Lafleur.	5/2145	09/17/15	ILS OR LOC/DME RWY 5, Amdt 4.
12–Nov–15	TN	Bristol/Johnson/Kingsport.	Tri-Cities Rgnl Tn/Va ..	5/2692	09/16/15	RNAV (GPS) RWY 5, Amdt 1A.
12–Nov–15	TX	Madisonville	Madisonville Muni	5/2950	09/08/15	RNAV (GPS) RWY 18, Orig-A.
12–Nov–15	TX	Madisonville	Madisonville Muni	5/2951	09/08/15	RNAV (GPS) RWY 36, Orig.
12–Nov–15	TX	Madisonville	Madisonville Muni	5/2952	09/08/15	VOR/DME RWY 18, Amdt 2A.
12–Nov–15	NC	Lincolnton	Lincolnton-Lincoln County Rgnl.	5/3181	09/08/15	NDB RWY 23, Amdt 3A.
12–Nov–15	NC	Lincolnton	Lincolnton-Lincoln County Rgnl.	5/3184	09/08/15	RNAV (GPS) RWY 5, Amdt 1A.
12–Nov–15	TX	Athens	Athens Muni	5/3455	09/10/15	NDB RWY 35, Amdt 4C.
12–Nov–15	PA	Allentown	Lehigh Valley Intl	5/3648	09/08/15	RNAV (GPS) RWY 13, Amdt 1.
12–Nov–15	PA	Allentown	Lehigh Valley Intl	5/3649	09/08/15	RNAV (GPS) RWY 31, Amdt 2.
12–Nov–15	PA	Allentown	Lehigh Valley Intl	5/3656	09/08/15	ILS OR LOC RWY 6, Amdt 23.
12–Nov–15	PA	Allentown	Lehigh Valley Intl	5/3659	09/08/15	RNAV (GPS) RWY 6, Amdt 1.
12–Nov–15	PA	Allentown	Lehigh Valley Intl	5/3662	09/08/15	ILS OR LOC/DME RWY 24, Amdt 1.
12–Nov–15	PA	Allentown	Lehigh Valley Intl	5/3663	09/08/15	RNAV (GPS) RWY 24, Amdt 1.
12–Nov–15	MN	Faribault	Faribault Muni	5/4326	09/08/15	RNAV (GPS) RWY 30, Amdt 1A.
12–Nov–15	MN	Faribault	Faribault Muni	5/4327	09/08/15	RNAV (GPS) RWY 12, Amdt 1A.
12–Nov–15	ND	Fargo	Hector Intl	5/4329	09/08/15	RNAV (GPS) RWY 9, Amdt 1A.
12–Nov–15	ND	Fargo	Hector Intl	5/4330	09/08/15	RNAV (GPS) RWY 27, Amdt 1A.
12–Nov–15	ND	Fargo	Hector Intl	5/4339	09/08/15	ILS OR LOC RWY 18, Orig-A.
12–Nov–15	ND	Fargo	Hector Intl	5/4340	09/08/15	RNAV (GPS) RWY 18, Amdt 1.
12–Nov–15	ND	Fargo	Hector Intl	5/4341	09/08/15	VOR/DME OR TACAN RWY 18, Amdt 1B.
12–Nov–15	ND	Fargo	Hector Intl	5/4366	09/08/15	RNAV (GPS) RWY 36, Orig-A.
12–Nov–15	ND	Fargo	Hector Intl	5/4367	09/08/15	VOR OR TACAN RWY 36, Orig-B.
12–Nov–15	ND	Fargo	Hector Intl	5/4368	09/08/15	ILS OR LOC RWY 36, Amdt 1A.
12–Nov–15	OH	Port Clinton	Carl R Keller Field	5/4485	09/17/15	Takeoff Minimums and (Obstacle) DP, Amdt 6.
12–Nov–15	PA	Reedsville	Mifflin County	5/4779	09/08/15	RNAV (GPS) RWY 6, Orig.
12–Nov–15	PA	Reedsville	Mifflin County	5/4780	09/08/15	LOC RWY 6, Amdt 8A.
12–Nov–15	PA	Reedsville	Mifflin County	5/4781	09/08/15	RNAV (GPS) RWY 24, Orig.
12–Nov–15	FL	Williston	Williston Muni	5/4932	09/09/15	RNAV (GPS) RWY 23, Orig.
12–Nov–15	FL	Williston	Williston Muni	5/4933	09/09/15	RNAV (GPS) RWY 5, Orig.
12–Nov–15	FL	Williston	Williston Muni	5/4936	09/09/15	VOR RWY 23, Amdt 1.
12–Nov–15	SC	Newberry	Newberry County	5/6291	09/10/15	RNAV (GPS) RWY 22, Orig.
12–Nov–15	SC	Newberry	Newberry County	5/6292	09/10/15	NDB RWY 22, Amdt 6A.
12–Nov–15	SC	Newberry	Newberry County	5/6293	09/10/15	RNAV (GPS) RWY 4, Orig.
12–Nov–15	FL	Marathon	The Florida Keys Marathon.	5/6806	09/10/15	Takeoff Minimums and (Obstacle) DP, Amdt 1A.
12–Nov–15	GA	Vidalia	Vidalia Rgnl	5/6816	09/10/15	RNAV (GPS) RWY 25, Amdt 2.
12–Nov–15	AZ	Nogales	Nogales Intl	5/7101	09/10/15	NDB OR GPS-C, Amdt 2C.
12–Nov–15	AZ	Nogales	Nogales Intl	5/7102	09/10/15	VOR OR GPS-A, Amdt 3B.
12–Nov–15	AZ	Nogales	Nogales Intl	5/7103	09/10/15	VOR/DME OR GPS-B, Amdt 2B.
12–Nov–15	KS	Mc Pherson	Mc Pherson	5/7358	09/17/15	RNAV (GPS) RWY 18, Orig.
12–Nov–15	KS	Mc Pherson	Mc Pherson	5/7359	09/17/15	RNAV (GPS) RWY 36, Orig.
12–Nov–15	KS	Mc Pherson	Mc Pherson	5/7360	09/17/15	VOR/DME RWY 36, Amdt 6.
12–Nov–15	TN	Bristol/Johnson/Kingsport.	Tri-Cities Rgnl Tn/Va ..	5/7392	09/16/15	RNAV (GPS) RWY 23, Amdt 1A.
12–Nov–15	TN	Bristol/Johnson/Kingsport.	Tri-Cities Rgnl Tn/Va ..	5/7417	09/16/15	ILS OR LOC RWY 5, Amdt 3A.
12–Nov–15	IA	Mason City	Mason City Muni	5/7778	09/08/15	RNAV (GPS) RWY 36, Amdt 1A.
12–Nov–15	IA	Mason City	Mason City Muni	5/7807	09/08/15	Takeoff Minimums and (Obstacle) DP, Orig.
12–Nov–15	FL	Palm Coast	Flagler County	5/8047	09/10/15	Takeoff Minimums and (Obstacle) DP, Amdt 1.
12–Nov–15	FL	Palm Coast	Flagler County	5/8048	09/10/15	RNAV (GPS) RWY 6, Amdt 1B.
12–Nov–15	FL	Palm Coast	Flagler County	5/8049	09/10/15	RNAV (GPS) RWY 11, Amdt 1A.
12–Nov–15	FL	Palm Coast	Flagler County	5/8056	09/10/15	RNAV (GPS) RWY 24, Orig-C.
12–Nov–15	FL	Palm Coast	Flagler County	5/8058	09/10/15	RNAV (GPS) RWY 29, Orig-C.
12–Nov–15	WI	Manitowish Waters	Manitowish Waters	5/8448	09/10/15	RNAV (GPS) RWY 32, Orig.
12–Nov–15	WI	Manitowish Waters	Manitowish Waters	5/8450	09/10/15	RNAV (GPS) RWY 14, Orig.
12–Nov–15	MI	West Branch	West Branch Community.	5/8471	09/10/15	RNAV (GPS) RWY 9, Orig.
12–Nov–15	MI	West Branch	West Branch Community.	5/8474	09/10/15	RNAV (GPS) RWY 27, Orig.
12–Nov–15	MI	West Branch	West Branch Community.	5/8476	09/10/15	VOR RWY 27, Orig-E.
12–Nov–15	OH	Columbus	Rickenbacker Intl	5/9069	09/16/15	ILS OR LOC RWY 5L, Amdt 1A.

AIRAC Date	State	City	Airport	FDC Number	FDC Date	Subject
12–Nov–15	KY	Bardstown	Samuels Field	5/9073	09/16/15	RNAV (GPS) RWY 2, Orig.
12–Nov–15	KY	Bardstown	Samuels Field	5/9076	09/16/15	RNAV (GPS) RWY 20, Orig.
12–Nov–15	GA	Lagrange	Lagrange-Callaway	5/9119	09/17/15	RNAV (GPS) RWY 31, Orig-A.
12–Nov–15	GA	Lagrange	Lagrange-Callaway	5/9125	09/17/15	ILS OR LOC RWY 31, Amdt 2.
12–Nov–15	MN	Ely	Ely Muni	5/9213	09/10/15	RNAV (GPS) RWY 30, Amdt 1A.

[FR Doc. 2015–25553 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31040; Amdt. No. 3663]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 16, 2015. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 16, 2015.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE., West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION:

This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part § 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the

regulatory text of the SIAPs, Takeoff Minimums or ODPS, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFRs and specifies the types of SIAPs, Takeoff Minimums and ODPS with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPS, the TERPS criteria were applied to the conditions existing or anticipated at the

affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC on September 25, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 12 NOVEMBER 2015

Arcata/Eureka, CA, Arcata, RNAV (GPS) RWY 32, Amdt 1C

Greenville, PA, Greenville Muni, RNAV (GPS–B, Orig

Greenville, PA, Greenville Muni, Takeoff Minimums and Obstacle DP, Orig

Greenville, PA, Greenville Muni, VOR–A, Amdt 2

Henderson, TX, Rusk County, NDB–B, Amdt 1, CANCELED

Luray, VA, Luray Caverns, Takeoff Minimums and Obstacle DP, Amdt 2
Lyndonville, VT, Caledonia County, Takeoff Minimums and Obstacle DP, Amdt 6

Effective 10 DECEMBER 2015

Monterey, CA, Monterey Rgnl, Takeoff Minimums and Obstacle DP, Amdt 8

Washington, DC, Washington Dulles Intl, CONVERGING ILS RWY 12, Amdt 6, CANCELED

Washington, DC, Washington Dulles Intl, CONVERGING ILS RWY 19C, Amdt 8, CANCELED

Washington, DC, Washington Dulles Intl, CONVERGING ILS RWY 19L, Amdt 8, CANCELED

Washington, DC, Washington Dulles Intl, CONVERGING ILS RWY 19R, Orig, CANCELED

Georgetown, DE, Sussex County, VOR RWY 4, Amdt 5A, CANCELED

Orlando, FL, Orlando Sanford Intl, ILS OR LOC RWY 27R, Amdt 3B

Toccoa, GA, Toccoa RG Letourneau Field, RNAV (GPS) RWY 3, Amdt 1

Toccoa, GA, Toccoa RG Letourneau Field, RNAV (GPS) RWY 21, Amdt 2

Toccoa, GA, Toccoa RG Letourneau Field, Takeoff Minimums and Obstacle DP, Amdt 3A

Toccoa, GA, Toccoa RG Letourneau Field, VOR RWY 21, Amdt 14

Toccoa, GA, Toccoa RG Letourneau Field, VOR/DME RWY 3, Amdt 3

Glasgow, KY, Glasgow Muni, SDF RWY 8, Amdt 11, CANCELED

Boston, MA, General Edward Lawrence Logan Intl, Takeoff Minimums and Obstacle DP, Amdt 14

Greenville, ME, Greenville SPB, NDB–A, Amdt 5, CANCELED

Old Town, ME, Dewitt Fld, Old Town Muni, NDB RWY 22, Amdt 6A, CANCELED

Asheville, NC, Asheville Rgnl, RADAR 1, Amdt 5A, CANCELED

Charlotte, NC, Charlotte/Douglas Intl, ILS OR LOC RWY 18L, Amdt 9

Concord, NC, Concord Rgnl, RNAV (GPS) RWY 2, Amdt 1

Trenton, NJ, Trenton Mercer, NDB RWY 6, Amdt 7A, CANCELED

Louisa, VA, Louisa County/Freeman Field, RNAV (GPS) RWY 9, Orig

Riverton, WY, Riverton Rgnl, RNAV (GPS) RWY 10, Amdt 2

Riverton, WY, Riverton Rgnl, RNAV (GPS) RWY 28, Amdt 1

Riverton, WY, Riverton Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2

Riverton, WY, Riverton Rgnl, VOR RWY 10, Amdt 10

Riverton, WY, Riverton Rgnl, VOR RWY 28, Amdt 10

[FR Doc. 2015–25555 Filed 10–15–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0948]

Drawbridge Operation Regulations; James River, Isle of Wight and Newport News, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the James River Bridge (US 17 and VA 258) across the James River, mile 5.0, between Isle of Wight and Newport News, VA. This deviation allows the bridge to remain in the closed-to-navigation position to facilitate work on electrical control and power wiring systems on the bridge.

DATES: This deviation is effective from 8 a.m. on October 16, 2015, until 8 p.m. on October 19, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0948], is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH”. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6222, email Hal.R.Pitts@uscg.mil.

SUPPLEMENTARY INFORMATION: The Virginia Department of Transportation, who owns and operates the James River Bridge (US 17 and VA 258), has requested a temporary deviation from the current operating regulations to facilitate work on electrical control and power wiring systems on the bridge. The bridge is a vertical lift draw bridge and has a vertical clearance in the closed position of 60 feet above mean high water.

The current operating schedule is set out in 33 CFR 117.5. Under this temporary deviation, the bridge will remain in the closed-to-navigation position from 8 a.m. on October 16, 2015 until 8 p.m. on October 19, 2015.

The James River is used by a variety of vessels including deep draft ocean-going vessels, U. S. government vessels, small commercial fishing vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with U. S. government and commercial waterway users.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

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

Dated: October 13, 2015.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2015-26358 Filed 10-15-15; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2015-0944]

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, South Branch of the Elizabeth River, Portsmouth and Chesapeake, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Belt Line Railroad Bridge across the South Branch of the Elizabeth River, mile 2.6, between Portsmouth and Chesapeake, VA. This deviation allows the bridge to remain in the closed-to-navigation position to facilitate a tie replacement project.

DATES: This deviation is effective without actual notice from October 16, 2015 until 6 p.m. on October 23, 2015. For the purposes of enforcement, actual notice will be used from 7 a.m. on

October 16, 2015, until October 16, 2015.

ADDRESSES: The docket for this deviation, [USCG-2015-0944], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398-6222, email Hal.R.Pitts@uscg.mil.

SUPPLEMENTARY INFORMATION: The Norfolk and Portsmouth Belt Line Railroad Company, who owns and operates the Belt Line Railroad Bridge, has requested a temporary deviation from the current operating regulations to facilitate a tie replacement project on the bridge. The bridge is a vertical lift draw bridge and has a vertical clearance in the closed position of 6 feet above mean high water.

The current operating schedule is set out in 33 CFR 117.997(a). Under this temporary deviation, the bridge will remain in the closed-to-navigation position from 7 a.m. to 6 p.m., except for scheduled daily openings at 9 a.m., 12 noon, and 3 p.m., from October 16, 2015 through October 23, 2015. During this temporary deviation, the bridge will operate per 33 CFR 117.997(a) from 6 p.m. to 7 a.m. The South Branch of the Elizabeth River is used by a variety of vessels including deep draft ocean-going vessels, U.S. government vessels, small commercial vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will be able to open for emergencies and there is no alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impacts caused by this temporary deviation.

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

Dated: October 13, 2015.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2015-26359 Filed 10-15-15; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2015-0240; FRL-9935-56-Region 9]

Approval of Implementation Plans; Arizona, Phoenix-Mesa; 2008 Ozone Standard Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the Arizona State Implementation Plan (SIP) concerning the emission inventory, emission statements, reasonably available control technology corrections and the vehicle inspection and maintenance requirements for the Phoenix-Mesa 2008 eight-Hour Ozone National Ambient Air Quality Standard (NAAQS) Marginal nonattainment area. We are approving these revisions under the Clean Air Act (CAA or the Act).

DATES: This rule is effective on December 15, 2015 without further notice, unless the EPA receives adverse comments by November 16, 2015. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number [EPA-R09-OAR-2015-0240] by one of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the on-line instructions.

2. *Email:* levin.nancy@epa.gov.

3. *Mail or deliver:* Nancy Levin (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Instructions: Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit <http://www.epa.gov/>

dockets/comments.html for further instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. For the full EPA public comment policy and general guidance on making effective comments, please visit <http://www.epa.gov/dockets/comments.html>.

Docket: Generally, documents in the docket for this action are available electronically at www.regulations.gov or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at www.regulations.gov, some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, (415) 972–3848, Levin.nancy@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us,” and “our” refer to the EPA.

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 - F. Offset Requirements
 - G. Transportation Conformity
- IV. Final Action
- V. Statutory and Executive Order Reviews

I. Background

On March 12, 2008, the EPA strengthened the primary and secondary eight-hour ozone NAAQS to 0.075 ppm (annual fourth-highest daily maximum eight-hour concentration, averaged over three years) (73 FR 16436).¹ In accordance with section 107(d) of the CAA, the EPA must designate an area “nonattainment” if it is violating the NAAQS or if it is contributing to a violation of the NAAQS in a nearby area. The EPA designated the Phoenix-

¹ Since the 2008 primary and secondary NAAQS for ozone are identical, for convenience, we refer to both as “the 2008 ozone NAAQS” or “the 2008 ozone standards.”

Mesa (hereinafter referred to as “Maricopa”) area as nonattainment for the 2008 ozone NAAQS on May 21, 2012, effective July 20, 2012 (77 FR 30088). The Maricopa nonattainment area (NAA), which includes a portion of Maricopa County and a portion of Pinal County, was classified by operation of law as a Marginal nonattainment area (40 CFR 81.303). The Arizona Department of Environmental Quality (ADEQ) submitted the “Maricopa Association of Governments 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area requirements for the Maricopa Nonattainment Area (June 2014)” (“MAG 2014 Eight-Hour Ozone Plan” or “Submittal”) on July 2, 2014.

The EPA proposed the 2008 ozone NAAQS SIP Requirements Rule (SRR) on June 6, 2013 (78 FR 34178) and finalized the SRR on March 6, 2015 (80 FR 12264, codified at 40 CFR part 51, subpart AA), effective April 6, 2015. The SRR both promulgated implementation requirements for the 2008 ozone NAAQS and revoked the 1997 ozone NAAQS.²

On August 27, 2015, the EPA proposed to reclassify the Maricopa NAA as Moderate for the 2008 ozone NAAQs because the Maricopa NAA failed to attain the 2008 ozone NAAQS by the Marginal area attainment deadline of July 20, 2015 (80 FR 51992). Should this action be finalized, the Maricopa NAA would be subject to additional requirements, including (1) an attainment demonstration; (2) provisions for reasonably available control technology (RACT) and reasonably available control measures (RACM); (3) reasonable further progress (RFP) reductions in volatile organic compounds (VOC) and/or nitrogen oxide (NO_x) emissions; (4) contingency measures; (5) a vehicle inspection and maintenance program; and (6) NO_x and VOC emission offsets at a ratio of 1.15 to 1 for major source permits (see 40 CFR part 51, subpart AA and CAA sections 182(b) and 172(c)). A SIP revision addressing all of these requirements would be due to the EPA by January 1, 2017.³

II. Procedural Requirements for Adoption and Submittal of SIP Revisions

CAA section 110(a)(1) and 110(l) require states to provide reasonable notice and public hearing prior to adoption of SIP revisions. Section 110(k)(1)(B) requires the EPA to

² The SRR revokes the 1997 NAAQS, but not all of the requirements for implementing the 1997 NAAQS.

³ 80 FR 51992, 51999.

determine whether a SIP submittal is complete within 60 days of receipt. Any plan that we have not affirmatively determined to be complete or incomplete will become complete six months after the day of submittal by operation of law. A finding of completeness does not approve the submittal as part of the SIP nor does it indicate that the submittal is approvable. It does start a 12-month clock for the EPA to act on the SIP submittal (see CAA section 110(k)(2)).

ADEQ’s Submittal documents the public review process followed by MAG and ADEQ in adopting the “MAG 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area Requirements for the Maricopa Nonattainment Area” prior to submittal to the EPA as a revision to the SIP (See Appendix B.1). In addition, ADEQ’s Submittal documents the adoption of the MAG 2014 Eight-Hour Ozone Plan by the MAG Regional Council and includes a letter dated June 27, 2014 from MAG to ADEQ, requesting that ADEQ submit the MAG 2014 Eight-Hour Ozone Plan to the EPA for approval.

Based on the documentation included in ADEQ’s Submittal, we find that the submittal of the MAG 2014 Eight-Hour Ozone Plan, as a SIP revision, satisfies the procedural requirements of sections 110(a)(1) and 110(l) of the Act requiring states to provide reasonable notice and public hearing prior to adoption of SIP revisions. The MAG 2014 Eight-Hour Ozone Plan became complete by operation of law on January 2, 2015 pursuant to section 110(k)(1)(B). The technical support document (TSD) for our action has more information on our evaluation.

III. Analysis of the State’s Submittal

For Marginal nonattainment areas, states are required to comply with sections 172(c) and 182(a) of the Act. Marginal areas have up to three years from the effective date of designation to attain the NAAQS (40 CFR 51.1103(a)). Unlike areas classified as Moderate and above, Marginal areas are not required to submit an attainment demonstration or RFP provisions (see CAA section 182(a) and 80 FR 12268). Below we summarize the CAA and SRR requirements, how they are addressed in the Submittal, and our recommended action. Please refer to the TSD in the docket for this action for additional information.

A. Base Year Emissions Inventory

1. Statutory and Regulatory Requirements

CAA section 182(a)(1) and 40 CFR 51.1115(a) require states to submit a “base year inventory” for each 2008 ozone nonattainment area within two years of the effective date of designation. This inventory must be “a comprehensive, accurate, current inventory of actual emissions from sources of VOC and NO_x emitted within the boundaries of the nonattainment area as required by CAA section 182(a)(1)” (40 CFR 51.1100(bb), see also CAA section 172(c)(3)). The inventory year must be selected consistent with

the baseline year for the RFP plan, which is typically the most recent calendar year for which a complete triennial inventory is required to be submitted to the EPA under the Air Emissions Reporting Requirements (AERR) (40 CFR part 51, subpart A) (see 40 CFR 51.1115(a), 51.1110(b)). The emission values in the base year must be “actual ozone season day emissions,” *i.e.* “an average day’s emissions for a typical ozone season work weekday.” (40 CFR 51.1115(c), 51.1100(cc)).

2. Summary of the State’s Submittal

The Maricopa County Air Quality Department (MCAQD) prepared a base year emissions inventory, with the

assistance of MAG, and MAG submitted the base year inventory as part of the MAG 2014 Eight-hour Ozone Plan.⁴ MCAQD selected 2011 as the base year. The base year inventory includes ozone season-day emissions from point sources, area sources, nonroad mobile sources, and on-road mobile sources. Appendix A, Exhibit 1 of the MAG 2014 Eight-Hour Ozone Plan includes a description of the methods used to estimate emissions for each category (or subcategory).

The following is a summary of the 2011 Maricopa NAA Emissions Inventory.⁵

MARICOPA NAA 2011 BASE YEAR EIGHT-HOUR OZONE SEASON DAY EMISSION INVENTORY
[July–September]

Category	VOC lbs/day	% of Total	NO _x lbs/day	% of Total
Point sources	4,908	1	15,407	3.1
Area sources:				
Fuel combustion	593	0.1	23,484	4.8
Industrial processes	17,452	4	1,490	0.3
Solvent use	166,557	34	0	0
Storage/transport	28,766	6	0	0
Waste treatment/disposal	838	0	316	0.1
Miscellaneous area sources	13,650	3	6,532	1.3
Mobile—Non road sources	111,798	23	141,444	28.8
Mobile—On road sources	148,186	30	301,824	61.5
Total (excluding biogenic) *	492,748	100	490,495	100.0

* Differences due to rounding.

The TSD for this action contains more information about how MCAQD developed the emission inventory (EI) data for each category of sources.

3. EPA Evaluation of the State’s Submittal

The EPA has reviewed the 2011 ozone season day base year inventory including emission estimates for point source, area source, nonroad and onroad sources. We find that MCAQD’s selection of 2011 as the base year is appropriate because 2011 was the most recent calendar year for which a complete triennial inventory was required to be submitted to the EPA under the AERR (see 40 CFR 51.30(b)).

We also find that the data elements in the base year inventory are “consistent with the detail” required by the AERR. Generally, MCAQD used published emission factors from EPA’s National Emissions Inventory,⁶ made assumptions consistent with the EPA’s Emission Inventory Improvement Program Guidance,⁷ and used the most recent EPA models available at the time of inventory preparation. In addition, the Submittal provides sufficient documentation and explanation to allow the EPA to make a determination on the acceptability of the base year inventory.

However, we believe that MCAQD’s initial selection of July–September as the basis for calculating the “ozone

season day emissions” was not appropriate because it was based on 1981–1991 exceedance data for a previous ozone NAAQS.⁸ Accordingly, we requested that MCAQD review more recent ozone monitoring data. Upon review of these data, MCAQD determined that the appropriate months to use to calculate ozone season day emissions are June–August.⁹ Therefore, MCAQD provided a “recast” ozone season day EI for June–August.¹⁰ The MCAQD’s “recast” analysis shows that, compared with the July–September EI, the June–August EI showed a small net increase in season day emissions for anthropogenic sources: VOC increased 0.41 and NO_x increased 2.15. MCAQD

⁴ MAG 2014 Eight-hour Ozone Plan, Table 1—Summary Table of Nonattainment Area Emissions from the Maricopa County Air Quality Department 2011 Periodic Emissions Inventory for Ozone Precursors, February 2014, page 5. See also Appendix A, Exhibit 1.

⁵ MAG 2014 Eight-Hour Ozone Plan, Table 1, pp. 5–6.

⁶ The National Emissions Inventory (NEI) is a comprehensive and detailed estimate of air emissions of air pollutants from all air emissions sources. The NEI is prepared every three years by the EPA based primarily upon emission estimates

and emission model inputs provided by State, Local and Tribal air agencies for sources in their jurisdictions, and supplemented by data developed by the EPA. See <http://www3.epa.gov/ttn/chief/eiinformation.html>.

⁷ See, e.g., EPA, Emissions Inventory Improvement Program (EIIP), Volume III, Chapter 1. Introduction to Area Source Emission Inventory Development (Revised Final January 2001), Chapter 11. Gasoline Marketing (Stage I and Stage II) (Revised Final January 2001); Chapter 18. Structure Fires (Revised Final January 2001), and Area Source Category Method Abstract—Leaking Underground Storage Tanks, May 2001.

⁸ See Appendix A, Exhibit 1: 2011 Periodic Emissions Inventory for Ozone Precursors for the Maricopa County, Arizona, Eight-Hour Ozone Nonattainment Area. Maricopa County Air Quality Department, February 2014. An “exceedance” is an ambient concentration that exceeds the relevant NAAQS.

⁹ Maricopa County Air Quality Department, 2011 Periodic Emissions Inventory for Ozone Precursors for the Maricopa County, Arizona, Eight-Hour Ozone Nonattainment Area, Addendum, August 2015, section 3.1.

¹⁰ *Ibid.* section 3.2.

also added emission reduction credits (ERCs) to the June–August EI for point sources. Total VOC ERCs were adjusted from 114.7 to 213.03 tons/year (1,167 lbs/season day) and total NO_x ERCs were adjusted from 9.8 to 14.14 tons/year (77.5 lbs/season day) to account for additional VOC and NO_x ERCs.¹¹

We agree with MCAQD that using June–August to calculate ozone season day emissions for the base year inventory is appropriate for the Maricopa NAA, given that it was the three-month period with the highest average Air Quality Index value and the greatest number of exceedances of the 2008 ozone standard in the NAA in 2011. However, in light of the relatively small differences in total anthropogenic emissions between the June–August 2011 and July–September 2011 periods, we do not believe it is necessary for MCAQD, MAG and ADEQ to submit a formal SIP revision reflecting the June–August period at this time. Accordingly, we find that the base year emission estimates approaches and methodologies are acceptable and that the state has met the requirements of the Act and the SRR with respect to base year inventories. We recommend that a revised 2011 season-day EI based on June–August data be included as part of a subsequent SIP revision to meet the CAA’s Moderate ozone nonattainment area requirements, as described above.

B. Emission Statements

1. Statutory and Regulatory Requirements

Section 182(a)(3)(B)(i) of the Act requires States to submit a SIP revision requiring owners or operators of stationary sources of VOC or NO_x to provide the State with statements of actual emissions from such sources. Statements must be submitted at least every year and must contain a certification that the information contained in the statement is accurate to the best knowledge of the individual certifying the statement. Section 182(a)(3)(B)(ii) allows States to waive the emission statement requirement for any class or category of stationary sources that emit less than 25 tons per year of VOCs or NO_x, if the state provides an inventory of emissions from such class or category of sources as part of the baseline or periodic inventory. This inventory must be based on the use of the emission factors established by the EPA or other methods acceptable to the EPA.

¹¹ ERCs from Penn Racquet Sports Inc. (March 6, 2009). See Addendum, Table A.1.

2. Summary of the State’s Submittal

ADEQ references three SIP-approved rules as meeting the requirements of CAA section 182(a)(3)(B): Maricopa County Rule 100, Section 500—Monitoring and Records, ADEQ Rule 18–2–327—Annual Emissions Inventory Questionnaire and Pinal County rule PG3–1–103—Annual EI questionnaire.

3. EPA Evaluation of the State’s Submittal

Maricopa County Rule 100 (Section 500, Subsection 503) (approved into the Arizona SIP on November 5, 2012 (77 FR 66405)) requires owners/operators of sources that emit NO_x or VOC to submit, upon request of the Control Officer, emission statements showing actual or estimated actual emissions of NO_x and VOC, containing (at a minimum) all information required by Consolidated Emissions Reporting Rule,¹² 40 CFR subpart A, appendix A, table 2a.¹³ Section 503 also requires that Emissions Statements be submitted annually. The Control Officer may waive this requirement for the owner/operator of any source that emits less than 25 tons per year of NO_x or VOC with an approved emission inventory for sources based on AP–42 or other methodologies approved by the EPA.

ADEQ Rule 18–2–327, Annual Emissions Inventory Questionnaire (approved into the Arizona SIP on November 5, 2012 (77 FR 66405)), requires every source subject to air permit requirements to complete and submit an annual emissions inventory questionnaire including facility contact information, process and control device descriptions, and a quantification of actual emissions of regulated air pollutants¹⁴ using the appropriate quantification method as described in the rule.

Pinal County Rule PG3–1–103 (approved into the Arizona SIP on December 20, 2000 (65 FR 79742)) requires every source that is subject to a permit or obtains an authorization to operate, to complete and submit to the Control Officer an annual emissions inventory questionnaire. The questionnaire must include the source’s name, address, contact information,

¹² The Consolidated Emissions Reporting Rule is now part of the AERR (see 73 FR 76539).

¹³ Appendix G of the Maricopa County Air Pollution Control Rules, section 4, specifies that 40 CFR, Subpart A, Appendix A, Table 2a is incorporated by reference as of July 1, 2014. Table 2a was revised on February 19, 2015 (80 FR 8787, 8790).

¹⁴ Regulated air pollutant is defined by SIP-approved ADEQ rule R18–2–101, section 120 to include NO_x and VOC. (See 40 CFR 52.120(c)(162)(i)(A)(2),

address, and process information (e.g., including design capacity, operations schedule, emission control devices).¹⁵

Based on the contents of these rules, we find that Arizona has met the requirements of CAA section 182(a)(3)(B) for emission statements.

C. Reasonably Available Control Technology Corrections

1. Statutory and Regulatory Requirements

Section 182(a)(2)(A) of the CAA requires the State to submit, within six months of classification under section 181(a), all rules and corrections to existing RACT rules that were required under section 172(b) of the old (pre-1990 Amendments) CAA. Newly designated nonattainment areas are not subject to the RACT “fix-ups” required by section 182(a)(2)(A) because they were not subject to section 172(b) of the old law (see 57 FR 13498, 13503).

2. Summary of the State’s Submittal

The Submittal lists the SIP-approved Rules that apply to source categories subject to CAA section 182(a)(2)(A) and notes that the EPA approved Arizona’s RACT demonstration for the Maricopa County 1-hour Serious Area Ozone NAA on June 14, 2005 (70 FR 34362).

3. EPA Evaluation of the State’s Submittal

As noted in the Submittal, the EPA previously determined that Arizona had met the VOC RACT requirements under section 182(a)(2)(A) for the Maricopa one-hour ozone NAA (see 70 FR 13435 and 70 FR 34363). Although the NAA for the 2008 eight-hour ozone standard is larger than that the one-hour NAA, only the original one-hour area is subject to the RACT correction requirement of 182(a)(2)(A). Therefore, we find that Arizona has met the requirements of CAA section 182(a)(2)(A) with respect to the Maricopa 2008 eight-hour ozone NAA.

D. Vehicle Inspection and Maintenance Programs

1. Statutory and Regulatory Requirements

Section 182(a)(2)(B)(i) of the Act requires the State to submit a revision, immediately after November 15, 1990, to correct any pre-1990 schedules for vehicle emission control inspection and

¹⁵ On September 27, 2006 ADEQ submitted an amendment to PG Rule 3–1–103, however, the change does not substantively change the rule. Rather it reflected ADEQ’s reclassification of Class A and Class B permits to Class I, Class II, and Class III. Under this amendment, the term “Class B permits” is replaced by “Class II or Class II permits.”

maintenance programs, immediately after November 15, 1990. In addition, section 182(a)(2)(B)(ii) requires that the State shall review, revise, update, and republish in the **Federal Register** the guidance for the States for motor vehicle inspection and maintenance (I/M) programs within 1 year of November 15, 1990. The EPA's I/M regulations are codified at 40 CFR part 51, subpart S ("Inspection/Maintenance Program Requirements"), sections 51.350 through 51.373. As explained in the preambles to proposed and final SRR, no new vehicle I/M programs are currently required for purposes of the 2008 ozone NAAQS (78 FR 34194–34196, 80 FR 12283).

2. Summary of the State's Submittal

The Submittal notes that the EPA approved ADEQ's Basic and Enhanced Vehicle Emissions Inspection and Maintenance Programs on January 22, 2003, and approved a statutory provision extending the State's vehicle emissions inspection program on December 21, 2009 (74 FR 67819).

3. EPA Evaluation of the State's Submittal

As noted in the Submittal, the EPA previously approved an "enhanced" I/M program that exceeds the requirements of section 182(a)(2)(B) for the Phoenix-Mesa nonattainment area (69 FR 2912 (January 22, 2003)). Therefore, we find that Arizona has met the requirements of CAA section 182(a)(2)(B) with respect to the Maricopa 2008 eight-hour ozone NAA.

E. Permit Programs: Nonattainment Area Preconstruction, New Source Review

1. Statutory and Regulatory Requirements

Section 182(a)(2)(C) of the Act, requires states to submit a SIP revision within two years after November 15, 1990 to require pre-construction permits for new or modified major stationary sources in the NAA, and to correct requirements regarding pre-1990 permit programs. However, as explained in the preambles to the EPA's final Phase 2 implementation rule for the 1997 eight-hour standard and the final SRR, the EPA considers the submission of new source review (NSR) SIPs due on November 15, 1992 to have fulfilled this CAA requirement (See 75 FR 71683, n. 110, and 80 FR 12267). Therefore, the EPA has concluded that the two-year deadline contained in CAA section 182(a)(2)(C)(i) does not apply to subsequent NSR SIPs for revised ozone standards, including the nonattainment

NSR SIPs for implementing the eight-hour ozone NAAQS. (Id.) Accordingly, the SRR at 40 CFR 51.1114 sets a deadline of three years from the date of designation for states to submit their nonattainment NSR program SIPs for the 2008 ozone NAAQS.

2. Summary of the State's Submittal

The Submittal describes the roles of ADEQ, MCAQD and PCAQCD in implementing the preconstruction permit program in the Maricopa NAA. In particular, the Submittal explains that ADEQ has permitting jurisdiction for the following stationary source categories: smelting of metal ores, coal-fired electric generating stations, petroleum refineries, Portland cement plants, and portable sources. ADEQ also has permitting jurisdiction over other major sources in Pinal County, but has delegated implementation of the major source program to PCAQCD, which implements ADEQ's major NSR rules. MCAQD has jurisdiction over other sources in Maricopa County. The Submittal also described various SIP revisions submitted by ADEQ to meet nonattainment NSR requirements.

3. EPA Evaluation of the State's Submittal

The EPA recently finalized a limited approval and limited disapproval of various rules that comprise ADEQ's NSR program.¹⁶ We expect that ADEQ will revise these rules in the near future. With regard to MCAQD's rules, we note that ADEQ had submitted MCAQD Rule 240—Permits for New Major Sources and Major Modifications to Existing Major Sources to the EPA on August 31, 1995, but withdrew it on April 25, 2014 in order to revise and resubmit it to the EPA for SIP approval. ADEQ published a proposed notice of rulemaking for amendments to Rule 240 and other related rules on August 31, 2015.¹⁷ Given the expected submittal of revised ADEQ and MCAQD NSR rules in the near future, we are deferring action on this element of the MAG 2014 Eight-Hour Ozone Plan at this time.

F. Offset Requirements

CAA Section 173 requires new and modified major sources in

¹⁶ Final rule, Revisions to Air Plan; Arizona; Stationary Sources; New Source Review (pre-publication version, signed June 29, 2015).

¹⁷ On July 31, 2015 the Arizona Secretary of State published a notice of proposed rulemaking to amend MCAQD's rules relating to NSR, including Rule 240. See Arizona Administrative Register (AAR) Vol. 21, Issue 31, page 1302 (July 31, 2015), available at: http://apps.azsos.gov/public_services/register/2015/31/28_county_notices.pdf. It also announced a 30-day comment period that ended August 31, 2015.

nonattainment areas to secure emissions reductions (*i.e.*, "offsets") to compensate for a proposed emissions increase. For Marginal areas, section 182(a)(4) of the Act sets a general offset ratio of 1.1 to 1 for total VOC and NO_x emission reductions as compared to VOC and NO_x emission increases. The Submittal references ADEQ Rule R18–2–404(f) and Maricopa County Air Pollution Control Regulations, Rule 240, Section 306.3 as fulfilling the requirements of CAA section 182(a)(4). Given the expected submittal of revised ADEQ and MCAQD NSR rules in the near future, we are deferring action on this element of the MAG 2014 Eight-Hour Ozone Plan at this time.

G. Transportation Conformity

The Submittal lists "Meet Transportation Conformity Requirements—CAA Section 176(c)" as a marginal area requirement. We note that motor vehicle emission budgets, used in transportation conformity determinations, are not required for marginal areas because such areas are not required to submit a "control strategy implementation plan revision."¹⁸ However, as noted above, the EPA has proposed to reclassify the Maricopa NAA to Moderate nonattainment. If the reclassification is finalized, MAG would be required to develop motor vehicle emission budgets as part of a Moderate area attainment demonstration. In the meantime, MAG may continue to rely on its emission budgets for the 1997 ozone NAAQS,¹⁹ which the EPA approved on September 17, 2014 (79 FR 55645). Accordingly, we are not taking further action on these budgets at this time.

IV. Final Action

The EPA is taking direct final action to approve the MAG 2014 Eight-Hour Ozone Plan with respect to the requirements of CAA section 182(a)(1), (2)(A) and (B), and (3)(B) and is deferring action with respect to the requirements of CAA sections 176(c) and 182(a)(2)(C) and (4). We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rule(s). If we receive adverse comments by November 16, 2015, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the

¹⁸ See 40 CFR 93.101.

¹⁹ See 40 CFR 93.109(c)(2).

comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on December 15, 2015.

V. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 15, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that the EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 25, 2015.

Jared Blumenfeld,
Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

- 2. Section 52.120 is amended by adding paragraph (c)(172) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *
(172) The following plan was submitted July 2, 2014, by the Governor's designee.

(i) [Reserved]
(ii) *Additional materials*.
(A) Arizona Department of Environmental Quality (ADEQ).

(1) *MAG 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area Requirements for the Maricopa Nonattainment Area* (June 2014), excluding:

(i) Sections titled "A Nonattainment Area Preconstruction Permit Program—CAA section 182(a)(2)(C)," "New Source Review—CAA, Title I, Part D," and "Offset Requirements: 1:1 to 1 (Ratio of Total Emission Reductions of Volatile Organic Compounds to Total Increased Emissions)—CAA Section 182(a)(4)" on pages 8 and 9 and section titled "Meet Transportation Conformity Requirements—CAA Section 176(c)" on pages 10 and 11.

(ii) Appendices A and B.

[FR Doc. 2015-26023 Filed 10-15-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0363; FRL-9933-98]

2-Propen-1-Aminium, N,N-Dimethyl-N-Propenyl-, Chloride, Homopolymer; 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 2-propen-1-aminium, *N,N*-dimethyl-*N*-propenyl-, chloride, homopolymer (PolyDADMAC, CAS No. 26062-79-3) when used as an inert ingredient under 40 CFR 180.940(a) as a dispersing aid in food contact surface sanitizing solutions at less than 0.6% by weight in the final product. Scientific & Regulatory Solutions, L.L.C., on behalf of SNF, 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 PolyDADMAC.

DATES: This regulation is effective October 16, 2015. Objections and requests for hearings must be received on or before December 15, 2015, 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-2015-0363, 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), West William Jefferson Clinton 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: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNNotices@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-2015-0363 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 December 15, 2015. 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-2015-0363, 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. Petition for Exemption

In the **Federal Register** of July 17, 2015 (80 FR 42462) (FRL-9929-13), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10750) by Scientific & Regulatory Solutions, L.L.C., 3450 Old Washington Rd #303, Waldorf, MD 20602 on behalf of SNF, Inc., 1 Chemical Plant Road, Riceboro, GA 31321. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of PolyDADMAC, (CAS No. 26062-79-3) when used as an inert ingredient as a dispersing aid in pesticide formulations at less than 0.6% by weight. That document referenced a summary of the petition prepared by Scientific & Regulatory Solutions, L.L.C., on behalf of SNF, Inc., 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 exemption is "safe."

Section 408(c)(2)(A)(ii) of FFDC A 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 FFDC A requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue 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 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 FFDC A section 408(c)(2)(A), and the factors specified in FFDC A 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 PolyDADMAC including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with PolyDADMAC 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 PolyDADMAC 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.

A single dose feeding study with rats classified PolyDADMAC as “slightly toxic” at a dose level of 5 milliliter/kilogram (mL/kg) (approx. 2,000 milligram/kilogram (mg/kg)). The results of two skin irritation studies performed with rabbits indicate that PolyDADMAC is not a skin irritant. In two eye irritation studies performed with PolyDADMAC on rabbits, the results indicate that the product was slightly irritating to the eyes and that the effects were totally reversed within 72 hours following exposure. In an eye study performed with PolyDADMAC on cultured fibroblasts, the results indicate that PolyDADMAC is slightly irritating. In a teratology study performed with Sprague-Dawley rats, the administration of 600 milligram/kilogram/day (mg/kg/day) of PolyDADMAC, and to a lesser extent, at the 450 and 150 mg/kg/day test groups, elicited a significant reduction in maternal food consumption during the first half of the dosing period. The NOAEL for PolyDADMAC on embryonic development is 600 mg/kg/day. A multi-generational study performed with PolyDADMAC using Sprague-Dawley rats dosed with 0.375, 12.5, and 125 mg/kg/day (oral gavage) showed no increase in reproductive failure, nor were there any effects upon the fertility index or any other F1 or F2 generation parameters. The inferred NOAEL from the study was 125 mg/kg/day. The two genotoxicity studies performed with PolyDADMAC were negative in both an Ames test and in a mouse micronucleus assay. There are no carcinogenicity studies available for PolyDADMAC. However, no significant systemic toxicity was observed in the teratology, multi-generational and mutagenicity toxicity studies. In the absence of significant systemic toxicity, and lack of mutagenicity concerns, PolyDADMAC is not likely 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 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 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>.

PolyDADMAC is a large molecular weight chemical which satisfies all of the TSCA Polymer Exemption Rule except for its cationic properties. Generally, high molecular weight polymers are unlikely to be absorbed significantly through any route of exposure. In the case of PolyDADMAC, this is evidenced by: No systemic toxicity up to 600 mg/kg/day in the teratology study, no systemic toxicity in the multi-generational reproduction study up to 125 mg/kg/day, and low acute toxicity. Therefore, no adverse effect level endpoints have been selected for PolyDADMAC, and EPA concludes that it is not necessary to assess quantitative dietary risk or risk from exposure via dermal or inhalation.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to PolyDADMAC, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from PolyDADMAC in food as follows: Acute dietary assessments take into account exposure estimates from dietary consumption of food and drinking water. Chronic dietary assessments take into account dietary food and drinking water as well as food contact surface sanitation uses. In the case of PolyDADMAC, there are no current or proposed crop pesticidal uses; therefore oral exposures from that route (including exposure through drinking water) are not expected. Dietary exposure to PolyDADMAC can occur through its use in food contact sanitizing solutions. However, PolyDADMAC is a large molecular weight chemical which is unlikely to be absorbed significantly through any route of exposure and no endpoints have been

selected for it. The Agency has not identified any concerns for carcinogenicity relating to PolyDADMAC; therefore, a cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water.* PolyDADMAC residues may be found in drinking water. However, since an endpoint of concern was not identified for the dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

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).

While there are no current or proposed residential uses for PolyDADMAC, it is possible that PolyDADMAC may be used as an inert ingredient in pesticide products for which residential exposures may result. However, in the case of PolyDADMAC no applicable endpoints of concern for residential exposures have been identified and a quantitative exposure assessment from residential exposures was not performed.

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 or exemption from 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 PolyDADMAC to share a common mechanism of toxicity with any other substances, and PolyDADMAC does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that PolyDADMAC 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 Food Quality Protection Act Safety Factor (FQPA 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.* Teratology and multi-generational studies in laboratory animals indicate that PolyDADMAC caused no increase in reproductive failure nor were there any PolyDADMAC related effects upon the fertility index or any other F1 or F2 generation parameters (e.g., litter size, pup weight, fertility and parturition, reproductive indices such as mating index, fecundity index, male or female fertility indices, etc.). Finally, there was no remarkable pathology noted upon necropsy of any of the test animals. Neurotoxicity was not observed in a reproduction/developmental screening study in rats where neurotoxicity parameters were evaluated.

3. *Conclusion.* Based on an assessment of PolyDADMAC, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and has conducted a qualitative assessment. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Determination of safety section. 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.

Based on the lack of any endpoints of concern, 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 PolyDADMAC residues.

V. Other Considerations

A. 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.

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 PolyDADMAC.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for PolyDADMAC (CAS No. 26062-79-3) when used as an inert ingredient as a dispersing aid in food contact surface sanitizing solutions at less than 0.6% by weight in the final product.

VII. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCFA 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 action 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 FFDCFA 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (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: October 7, 2015.

Susan Lewis,

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 § 180.940(a), add alphabetically the inert ingredient “2-propen-1-aminium, *N,N*-dimethyl-*N*-propenyl-, chloride, homopolymer (CAS No. 26062–79–3)” to the table to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *
(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
* * * * *	* * * * *	* * * * *
2-propen-1-aminium, homopolymer.	<i>N,N</i> -dimethyl- <i>N</i> -propenyl-, chloride, 26062–79–3	When ready for use, the end-use concentration is not to exceed 0.6%.
* * * * *	* * * * *	* * * * *

* * * * *
[FR Doc. 2015–26297 Filed 10–15–15; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 2, 5, 11, 107, 113, 114, 117, 125, 159, 162, 175, and 180

[Docket No. USCG–2015–0867]

Shipping; Technical, Organizational, and Conforming Amendments

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule makes non-substantive technical, organizational, and conforming amendments to existing

regulations throughout Title 46 of the Code of Federal Regulations. This rule will have no substantive effect on the regulated public.

DATES: This final rule is effective October 16, 2015.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2015–0867, which is available at <http://regulations.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this final rule, call or email Mr. Paul Crissy, Coast Guard; telephone 202–372–1093, email Paul.H.Crissy@uscg.mil.

SUPPLEMENTARY INFORMATION:

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I. Abbreviations

- CFR Code of Federal Regulations
- DHS Department of Homeland Security
- E.O. Executive Order
- FR Federal Register
- OMB Office of Management and Budget
- Pub. L. Public Law
- § Section symbol
- U.S.C. United States Code

II. Regulatory History

We did not publish a notice of proposed rulemaking for this rule. Under 5 U.S.C. 553(b)(A), the Coast Guard finds that this rule is exempt from notice and comment rulemaking requirements, because these changes involve rules of agency organization, procedure, or practice. In addition, the Coast Guard finds that notice and comment procedures are unnecessary under 5 U.S.C. 553(b)(B), as this rule consists only of corrections and editorial, organizational, and conforming amendments, and that these changes will have no substantive effect on the public. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that, for the same reasons, good cause exists for making this final rule effective upon publication in the **Federal Register**.

III. Basis and Purpose

On the 1st of October each year, the printed editions of Titles 46 and 49 of the Code of Federal Regulations (CFR) are re-codified. This rule, which becomes effective October 16, 2015, makes technical and editorial corrections throughout Title 46. There are no technical or editorial corrections for Title 49 this year. This rule does not create or change any substantive requirements.

IV. Discussion of the Rule

Each year, the Coast Guard issues technical, organizational, and conforming amendments to existing regulations in Titles 46 and 49 of the CFR. These annual “technical amendments” provide the public with more accurate and current regulatory information, but do not change the impact on the public of any Coast Guard regulations. This rule makes no changes to Title 49.

This rule makes changes in the following sections of Title 46 in the CFR:

Section 2.75–25(c)(3): Change “in the **Federal Register**” to “on the Coast Guard’s Maritime Information eXchange Web site at <http://cgmix.uscg.mil/equipment>” to reflect the accurate location where the Coast Guard publishes the approval and listing of recognized laboratories. The change updates an outdated location.

Section 5.903(b): Change the mailing address to reflect the U.S. Coast Guard Office of Investigations and Analysis as the office for submitting applications.

Section 11.329(e): Remove the table in § 11.329(e) that is titled “Table 1 to § 11.327(d).” The same Table 1 correctly appears in § 11.327(d), but it has been erroneously duplicated in

§ 11.329(e). Table 1 to § 11.329(e) remains unchanged.

Sections 107.111, 114.400(b), 125.160, 159.005–13(a)(4), 175.400: Change the reference to the location where the Coast Guard publishes a listing of current and formerly approved equipment and materials. The change updates an outdated location.

Section 113.25–9(a): Change the term “windless” to “windlass.” The change corrects a typographical error.

Sections 117.68(a)(1), 117.68(b)(1), 117.68(c)(2)(ii), 117.68(c)(2)(iii), 117.70(b)(1), 117.70(d)(1), 117.71(c), 180.68(a)(1), 180.68(c)(2)(ii), 180.68(c)(2)(iii), 180.70(b)(1), 180.70(d)(1), 180.71(c), 180.75(a): Add a reference to the relevant approval standard for equipment carried on vessels subject to the International Convention for the Safety of Life at Sea (SOLAS), 1974, as an option for compliance. The SOLAS standards have already routinely been approved by the Coast Guard as an “other standard specified by the Commandant.” The change will provide clarity for the regulated public, eliminating duplicative approval requests.

Section 162.060–10(b)(1): Change “manufacturer” to “manufacturer or independent laboratory” to reflect the fact that the independent laboratory is typically the entity that submits requests for approval of alternatives as equivalent to the regulatory requirements.

Section 162.060–42(a)(2): Change the reference from “requirements in paragraph (b) of this section” to “requirements in paragraph (a)(1) of this section.” Section 162.060–42(a)(2) discusses the ability of an independent laboratory to reject a manufacturer’s proposed ballast water management system if the system does not meet the requirements listed in another paragraph in that section. Paragraph (b) is an incorrect reference paragraph because it does not list requirements for the manufacturer’s system; instead, it is a requirement for the independent laboratory. Paragraph (a)(1) is the correct reference paragraph because it lists the relevant requirements. The change corrects a typographical error.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes or E.O.s.

A. Regulatory Planning and Review

Executive Orders 13563 and 12866 direct agencies to assess the costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget. Because this rule involves non-substantive changes and internal agency practices and procedures, it will not impose any additional costs on the public. The benefit of the non-substantive changes is increased clarity of regulations.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), rules exempt from the notice and comment requirements of the Administrative Procedure Act are not required to examine the impact of the rule on small entities. Nevertheless, we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

There is no cost to this final rule, and we do not expect it will have an impact on small entities because the provisions of this rule are technical and non-substantive. It will have no substantive effect on the public and will impose no additional costs. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Mr. Paul Crissy by phone at 202–372–1093 or via email at Paul.H.Crissy@uscg.mil. The

Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

D. Collection of Information

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

E. Federalism

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

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any 1 year. Though this final rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This final rule will not cause a taking of private property or otherwise have taking implications under E.O. 12630 ("Governmental Actions and Interference with Constitutionally Protected Property Rights").

H. Civil Justice Reform

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

I. Protection of Children

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

J. Indian Tribal Governments

This final rule does not have tribal implications under E.O. 13175 ("Consultation and Coordination with Indian Tribal Governments"), because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this final rule under E.O. 13211 ("Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use"). We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of OMB's Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

L. Technical Standards

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

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

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and

Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2 and figure 2-1, paragraph (34)(a) of the Instruction. This final rule involves amendments to regulations that are editorial or procedural. An environmental analysis checklist and a categorical exclusion determination are available in the docket for this final rule where indicated under **ADDRESSES**.

List of Subjects

46 CFR Part 2

Marine safety, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 5

Administrative practice and procedure, Alcohol abuse, Drug abuse, Investigations, Seamen.

46 CFR Part 11

Penalties, Reporting and recordkeeping requirements, Schools, Seamen.

46 CFR Part 107

Marine safety, Oil and gas exploration, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 113

Communications equipment, Fire prevention, Vessels.

46 CFR Part 114

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Parts 117 and 180

Marine safety, Passenger vessels.

46 CFR Part 125

Administrative practice and procedure, Cargo vessels, Hazardous materials transportation, Marine safety, Seamen.

46 CFR Part 159

Business and industry, Laboratories, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 162

Fire prevention, Marine safety, Oil pollution, Reporting and recordkeeping requirements.

46 CFR Part 175

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR parts 2, 5, 11, 107, 113, 114, 117, 125, 159, 162, 175, and 180 to read as follows:

PART 2—VESSEL INSPECTIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: Sec. 622, Pub. L. 111–281; 33 U.S.C. 1903; 43 U.S.C. 1333; 46 U.S.C. 2103, 2110, 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277, sec. 1–105; Department of Homeland Security Delegation No. 0170.1(I)(77), (90), (92)(a), (92)(b).

§ 2.75–25 [Amended]

■ 2. In § 2.75–25(c)(3), remove the text “in the **Federal Register**” and add, in its place, the text “on the Coast Guard’s Maritime Information eXchange Web site at <http://cgmix.uscg.mil/equipment>”.

PART 5—MARINE INVESTIGATION REGULATIONS—PERSONNEL ACTION

■ 3. The authority citation for part 5 continues to read as follows:

Authority: 46 U.S.C. 2103, 7101, 7301, 7701; Department of Homeland Security Delegation No. 0170.1.

■ 4. Revise § 5.903(b) to read as follows:

§ 5.903 Application procedures.

* * * * *

(b) The completed application and letter must be addressed to the U.S. Coast Guard Office of Investigations and Analysis, Commandant (CG–INV–1), U.S. Coast Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7501, and must be delivered in person to the nearest Officer in Charge, Marine Inspection.

* * * * *

PART 11—REQUIREMENTS FOR OFFICER ENDORSEMENTS

■ 5. The authority citation for part 11 continues to read as follows:

Authority: 14 U.S.C. 633; 31 U.S.C. 9701; 46 U.S.C. 2101, 2103, and 2110; 46 U.S.C. chapter 71; 46 U.S.C. 7502, 7505, 7701, 8906, and 70105; E.O. 10173; Department of Homeland Security Delegation No. 0170.1. Section 11.107 is also issued under the authority of 44 U.S.C. 3507.

§ 11.329 [Amended]

■ 6. In § 11.329(e), remove Table 1 to § 11.327(d).

PART 107—INSPECTION AND CERTIFICATION

■ 7. The authority citation for part 107 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3306, 3307; 46 U.S.C. 3316; Department of Homeland Security Delegation No. 0170.1; § 107.05 also issued under the authority of 44 U.S.C. 3507.

§ 107.111 [Amended]

■ 8. In § 107.111 in the definition of “Approval series” following the text “A listing of”, remove the text “approved equipment, including all of the approval series, is published periodically by the Coast Guard in Equipment Lists (COMDTINST M16714.3 series), available from the Superintendent of Documents.” and add, in its place, the text “current and formerly approved equipment and materials may be found on the Internet at: <http://cgmix.uscg.mil/equipment>”.

PART 113—COMMUNICATION AND ALARM SYSTEMS AND EQUIPMENT

■ 9. The authority citation for part 113 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Department of Homeland Security Delegation No. 0170.1.

§ 113.25–9 [Amended]

■ 10. In § 113.25–9(a) following the words “passageways in cargo areas, steering gear rooms,” remove the word “windless” and add, in its place, the word “windlass”.

PART 114—GENERAL PROVISIONS

■ 11. The authority citation for part 114 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. App. 1804; Department of Homeland Security Delegation No. 0170.1; § 114.900 also issued under 44 U.S.C. 3507.

§ 114.400 [Amended]

■ 12. In § 114.400(b), in the definition of “Approval series” following the text “A listing of”, remove the text “approved equipment, including all of the approval series, is published periodically by the Coast Guard in Equipment Lists (COMDTINST M16714.3 series), available from the Superintendent of Documents.” and add, in its place, the text “current and formerly approved equipment and materials may be found on the Internet at: <http://cgmix.uscg.mil/equipment>”.

PART 117—LIFESAVING EQUIPMENT AND ARRANGEMENTS

■ 13. The authority citation for part 117 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 117.68 [Amended]

■ 14. Amend § 117.68 as follows:

■ a. In paragraphs (a)(1), (b)(1), and (c)(2)(ii) following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.121”; and

■ b. In paragraph (c)(2)(iii), following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.122”.

§ 117.70 [Amended]

■ 15. Amend § 117.70 as follows:

■ a. In paragraph (b)(1) following the text “specified by the Commandant”, add the text “, including, but not limited to, approval series 160.150”; and

■ b. In paragraph (d)(1) following the text “specified by the Commandant”, add the text “, including, but not limited to, approval series 160.110”.

§ 117.71 [Amended]

■ 16. In § 117.71(c), following the text “specified by the Commandant”, add the text “, including, but not limited to, approval series 160.155 or 160.176”.

PART 125—GENERAL

■ 17. The authority citation for part 125 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3307; 49 U.S.C. App. 1804; sec. 617, Pub. L. 111–281, 124 Stat. 2905; Department of Homeland Security Delegation No. 0170.1.

§ 125.160 [Amended]

■ 18. In § 125.160 in the definition of “Approval series” following the text “A listing of”, remove the text “approved equipment, including all of the approval series, is published periodically by the Coast Guard in Equipment Lists (COMDTINST M16714.3 series), available from the Superintendent of Documents.” and add, in its place, the text “current and formerly approved equipment and materials may be found on the Internet at: <http://cgmix.uscg.mil/equipment>”.

PART 159—APPROVAL OF EQUIPMENT AND MATERIALS

■ 19. The authority citation for part 159 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; 49 CFR 1.45, 1.46; Section 159.001–9 also issued under the authority of 44 U.S.C. 3507.

■ 20. Revise § 159.005–13(a)(4) to read as follows:

§ 159.005–13 Equipment or material: Approval.

(a) * * *

(4) Publishes a record of the approval in the Coast Guard Maritime Information Exchange (CGMIX). A listing of current and formerly approved equipment and materials may be found on the Internet at: <http://cgmix.uscg.mil/equipment>.

* * * * *

PART 162—ENGINEERING EQUIPMENT

■ 21. The authority citation for part 162 continues to read as follows:

Authority: 33 U.S.C. 1321(j), 1903; 46 U.S.C. 3306, 3703, 4104, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

§ 162.060–10 [Amended]

■ 22. § 162.060–10(b)(1), after the text “practicable or applicable, a manufacturer”, add the text “or independent laboratory”.

§ 162.060–42 [Amended]

■ 23. In § 162.060–42(a)(2) following the text “requirements in paragraph”, remove the text “(b)” and add, in its place, the text “(a)(1)”.

PART 175—GENERAL PROVISIONS

■ 24. The authority citation for part 175 continues to read as follows:

Authority: 46 U.S.C. 2103, 3205, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. App. 1804; Department of Homeland Security Delegation No. 0170.1; § 175.900 also issued under 44 U.S.C. 3507.

§ 175.400 [Amended]

■ 25. In § 175.400 in the definition of “Approval series” following the text “A listing of”, remove the text “approved equipment, including all of the approval series, is published periodically by the Coast Guard in Equipment Lists (COMDTINST M16714.3 series), available from the Superintendent of Documents.” and add, in its place, the text “current and formerly approved equipment and materials may be found on the Internet at: <http://cgmix.uscg.mil/equipment>.”.

PART 180—LIFESAVING EQUIPMENT AND ARRANGEMENTS

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

Authority: 46 U.S.C. 2104, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 180.68 [Amended]

■ 27. Amend § 180.68 as follows:
 ■ a. In paragraph (a)(1), following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.121”;
 ■ b. In paragraph (c)(2)(ii), after the text “specified by the Commandant”, add the text “, including, but not limited to, approval series 160.121”;
 ■ c. In paragraph (c)(2)(iii), after the text “or other standard specified by the Commandant”, add the text “, including, but not limited to, approval series 160.122”.

§ 180.70 [Amended]

■ 28. Amend § 180.70 as follows:
 ■ a. In paragraph (b)(1), following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.150”;
 ■ b. In paragraph (d)(1), following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.110”.

§ 180.71 [Amended]

■ 29. In § 180.71(c), following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.155 or 160.176”.

§ 180.75 [Amended]

■ 30. In § 180.75(a), following the text “specified by the Commandant” add the text “, including, but not limited to, approval series 160.112”.

Katia Kroutil,

Chief, Office of Regulations and Administrative Law, U.S. Coast Guard.

[FR Doc. 2015–26119 Filed 10–15–15; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 12

[PS Docket No. 14–174; FCC 15–98]

Ensuring Continuity of 911 Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Federal Communications Commission (FCC or Commission) adopts rules to promote continued access to 911 during commercial power outages by requiring providers of facilities-based, fixed residential voice services, which are not line powered, to offer subscribers the option to purchase a backup solution capable of 8 hours of standby power, and within three years, an additional solution capable of 24 hours of standby power. The item also promotes consumer education and choice by requiring providers of covered services to disclose to subscribers the following information: availability of backup power sources; service limitations with and without backup power during a power outage; purchase and replacement options; expected backup power duration; proper usage and storage conditions for the backup power source; subscriber backup power self-testing and monitoring instructions; and backup power warranty details, if any.

DATES: Effective dates: This rule is effective October 16, 2015, except for § 12.5(b)(1), which is effective February 16, 2016; § 12.5(b)(2), which is effective February 13, 2019; and § 12.5(d), which is effective 120 days after date the Commission announces approval from the Office of Management and Budget. The Commission will announce the effective date for § 12.5(d) with a document in the **Federal Register**.

Compliance dates: Section 12.5(b)(1), for providers with fewer than 100,000 domestic retail subscriber lines on August 11, 2016; and § 12.5(d), for providers with fewer than 100,000 domestic retail subscriber lines 300 days after date the Commission announces approval from the Office of Management and Budget. The Commission will announce the compliance date for § 12.5(d) with a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Public Safety and Homeland Security Bureau, Linda M. Pintro, at (202) 418–7490 or linda.pintro@fcc.gov. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Nicole Ongele at (202) 418–2991 or send an email to PRA@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s *Report and Order (R&O)* in PS Docket No. 14–174, released on August 7, 2015. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554, or online

at <https://www.fcc.gov/document/ensuring-continuity-911-communications-report-and-order>.

I. Introduction

1. In this *Report and Order*, the Federal Communications Commission (FCC or Commission) takes important steps to ensure continued public confidence in the availability of 911 service by providers of facilities-based fixed, residential voice services in the event of power outages.

2. For over one hundred years, consumers have trusted that they will hear a dial tone in an emergency even when the power is out. Now, as networks transition away from copper-based, line-powered technology, many are aware of the innovation this transition has spurred in emergency services, but many consumers, remain unaware that they must take action to ensure that dial tone's availability in the event of a commercial power outage. The Commission's own consumer complaints portal reveals frustration over the failure of service providers to adequately inform subscribers about how to self-provision backup power in order to access 911 services in a power outage. This period of transition has the potential to create a widespread public safety issue if unaddressed.

3. Accordingly, we create new section 12.5 of our rules to place limited backup power obligations on providers of facilities-based fixed, residential voice services that are not line-powered to ensure that such service providers meet their obligation to provide access to 911 service during a power outage, and to provide clarity for the role of consumers and their communities should they elect not to purchase backup power. To be sure, many providers of residential voice communications already offer some level of backup power to consumers. However, the vital importance of the continuity of 911 communications, and the Commission's duty to promote "safety of life and property through the use of wire and radio communication," favor action to ensure that all consumers understand the risks associated with non-line-powered 911 service, know how to protect themselves from such risks, and have a meaningful opportunity to do so. Specifically, we require all providers of facilities-based, fixed, voice residential service that is not line powered—including those fixed applications of wireless service offered as a "plain old telephone service" (POTS) replacement—to offer new subscribers the option to purchase a backup solution that provides consumers with at least 8 hours of standby power during

a commercial power outage, which will enable calls to 911. In addition, we require these providers to offer, within three years of the effective date of the eight hour obligation, at least one option that provides a minimum of 24 hours of 911 service.

4. Additionally, we require all providers of facilities-based, fixed, voice residential service that is not line-powered to notify subscribers, at the point of sale and annually thereafter until September 1, 2025, of the availability of backup power purchasing options, use conditions and effect on power source effectiveness, power source duration and service limitations, testing and monitoring, and replacement details. Additionally, we direct the PSHSB to work with CGB to develop, prior to the implementation date of these rules for smaller providers, as herein defined, non-binding guidance with respect to the required notifications to subscribers. We limit these obligations to ten years as that should be enough time to ensure that overall consumer expectations regarding residential voice communications are aligned with ongoing technology transitions.

5. Finally, we encourage covered providers to conduct tailored outreach to state and local disaster preparedness entities to ensure that consumables and rechargeable elements associated with backup power technical solutions deployed in their area are well understood so that communities may prioritize restocking and/or recharging in response to extended power outages.

II. Background

6. Our Nation's communications infrastructure and the services available to consumers are undergoing technology transitions. The Commission has recognized that these transitions will bring enormous benefits to consumers, but also that they raise important questions about how to appropriately carry out our obligations set forth in the Communications Act, including promoting public safety and national security, and protecting consumers.

7. To further these statutory objectives, in November 2014, the Commission adopted a *Notice of Proposed Rulemaking (NPRM)* seeking to ensure reliable backup power for consumers . . . Specifically, the Commission sought comment on the "communications services we should include within the scope of any backup power requirements we may adopt" and "propose[d] that any potential requirements would apply to facilities-based, fixed voice residential services, such as interconnected Voice over

Internet Protocol (VoIP), that are not line-powered by the provider." The Commission proposed that "providers should assume responsibility for provisioning backup power that is capable of powering network equipment at the subscriber premises during the first 8 hours of an outage" but sought comment on what should happen in the event of an extended commercial power outage. The Commission also recognized the importance of outreach to consumers on the effect of commercial power outages to their communications services and sought comment on effective consumer notification.

III. Discussion

8. Communications services play an essential role in the delivery of public safety services, particularly 911, and that role is especially prominent during emergencies that lead to power outages. In the NPRM in this proceeding, we sought comment on the means to ensure that consumers have access to minimally essential communications, including 911 calls and telephone-based alerts and warnings, during a loss of commercial power. In this *Report & Order*, we take steps toward that goal by establishing clear lines of responsibility for ensuring continued 911 service during such commercial power outages and by: (1) Establishing a phased-in obligation for the offering of backup power solutions to consumers; and (2) requiring covered providers to engage in disclosure of the risks associated with these outages and steps consumers may take to address those risks.

9. As discussed in greater detail below, we require that providers of non-line-powered facilities-based, fixed, voice residential service, including fixed wireless service intended as POTS replacement, offer, at the subscriber's option and expense, a backup power solution that provides 911 access for 8 hours in the event of commercial power loss. Within three years, providers must also offer a 24-hour backup power solution. We also require covered providers to explain at point of sale how the subscriber may extend the provision of backup power during longer, multi-day outages through devices such as solar chargers, car chargers or mobile charging stations and to direct customers to sources of such equipment. No provider will be required to install backup power unless requested by, and at the expense of, the subscriber, and no subscriber will be forced to purchase unwanted equipment. Rather, our rules will ensure that subscribers who so elect can obtain backup power simply and conveniently when activating a covered

service. In addition, in order to ensure that consumers are adequately informed in determining whether to make this election, we adopt disclosure requirements designed to ensure that subscribers are aware of the backup power options available for their service, including installation and other usage instructions. We also encourage, but do not require, providers to conduct tailored outreach to state and local disaster preparedness entities to ensure that consumables associated with their backup power technical solutions are well understood so that communities may prioritize restocking and/or recharging in support of extended power outages.

A. Need for Line Powering or an Alternative Source of Power During Outages

10. In the *NPRM*, we noted that, in the past, consumers have relied upon service providers for backup power for their residential landline phones. That is, equipment on the subscriber premises of those still served by copper networks continued to work during commercial power outages as long as the handset or other subscriber premises equipment did not need to be plugged into an electrical outlet to function. We proposed and sought comment on steps we could take to safeguard continuity of communications throughout a power outage across networks that provide residential fixed voice service used to dial 911, including the possible adoption of new rules. Based on the record of this proceeding, we conclude that in order to ensure the availability of 911 service in the provision of facilities-based, fixed, voice residential services during power outages, we must adopt rules to require, among other things, either line powering or (at the subscriber's option and expense) an alternative means of maintaining 911 access during commercial power outages.

11. During a power outage, many subscribers must rely on a battery backup, or an uninterruptible power supply (UPS), to ensure that their service will continue to operate. That is, many subscribers cannot rely on the availability of continuous power that is sufficient to provide basic telephony indefinitely in their homes. Specifically, modern fiber and cable networks do not provide power to operate necessary equipment at the subscriber location, including network devices (e.g., cable modems, optical network terminals) and telephones. The deployment of a VoIP service requires that analog voice signals be converted to IP, using a voice codec. The most commonly deployed

model for VoIP services in the United States places the Analog Telephone Adapter (ATA) in a network device that is installed inside of the living unit. This ATA function is commonly used in hybrid fiber coax cable networks that use embedded multimedia terminal adapters (eMTA), twisted pair telephone (DSL) networks and increasingly Fiber-to-the-Home (FTTH) Optical Network Units (ONUs), also called Optical Network Terminals (ONTs). Voice codecs support voice, fax, and other legacy TDM services over IP, and their function is sometimes referred to as the ATA. Network devices with the embedded ATA function are powered directly by AC power or through a UPS that converts AC to DC power. According to the CSRIC report, in other use cases, the ATA function is being placed in consumer owned devices, creating more challenges for battery backup of VoIP services.

12. Given that consumers are increasingly relying on new types of service for residential voice communications, and that in many areas traditional line-powered 911 service is now, or is soon likely to be, no longer be available, the *NPRM* asked whether it was reasonable for providers to continue to bear primary responsibility for backup power, and if so, to what extent. We also stated that it was our intention to: (1) Establish clear expectations for both providers and subscribers as to their responsibilities throughout the course of an outage; and (2) minimize potential for lapses in service because of subscriber confusion or undue reliance on the provider with respect to backup power for equipment at the subscriber premises. The *NPRM* communicated a desire to adopt baseline requirements for ensuring continuity of power for devices at the subscriber location during commercial power outages. We acknowledged that backup power is not solely a copper retirement issue. Thus, we intended to address backup power at the subscriber premises also for those who have already migrated or been transitioned to an IP-based network.

13. We adopt the rules that follow because we believe that it is essential for all consumers to be able to access 911 emergency services during commercial power outages, especially those outages caused by catastrophic storms or other unpredictable events, and to understand how to do so. Ensuring the ability to maintain such service is a vital part of our statutory mandate to preserve reliable 911 service, and more generally, our statutory goal to promote "safety of life and property through the use of wire and radio communication." We agree

with the National Association of State Utility Consumer Advocates (NASUCA) that it is unlikely that our concerns would be adequately addressed without the adoption of regulatory requirements. We are supported in our conclusion by commenters such as the Pennsylvania Public Utility Commission (PA PUC), which urges the Commission to adopt baseline requirements for ensuring continuity of power during commercial power outages applicable to providers of interconnected VoIP-based services that do not provide line power at their central office, but rather rely on backup power.

14. Specifically, we find that public safety officers, first responders and other public officials have a need to communicate with citizens through whatever means possible, and 911 service plays an important role in this regard. Indeed, consumer advocates and 911 providers emphasize the need to adopt robust backup power requirements to ensure public safety. For example, Public Knowledge notes that right now consumers of traditional landline service are "guaranteed backup power during power outages" and "many consumers keep their landline service specifically to retain this feature." Public Knowledge further states that, "[w]ith the advent of cordless phones the only time the consumer worried about backup batteries was for their cordless phone or they simply retained a traditional phone to use during emergencies."

15. NASUCA and many other commenters agree that Commission action will help preserve consumers' ability to access 911 service. Specifically, NASUCA "fully supports the Commission's determination to ensure reliable backup power for consumers of IP-based voice and data services across networks that provide residential, fixed service that substitutes for and improves upon the kind of traditional telephony used by people to dial 911." According to NASUCA, "[b]ackup power requirements will help ensure that service will continue in a power outage." The National Association of State 911 Administrators (NASNA) similarly observes that "[t]he transition from legacy copper loops to other network technologies means that an important safety net—Central Office provisioning of line power to the subscriber premises—will disappear unless the Commission takes action to mitigate it." The Communications Workers of America (CWA) asserts that CWA, consumer organizations, state regulatory commissions, and public safety associations "support Commission proposals to facilitate the

transition to high-speed broadband networks, protect consumers and promote public safety by *upgrading* Commission rules regarding back-up power, network changes, and service discontinuance.”

16. We agree that this period of transition gives rise to the need for “upgrading Commission rules.” We observe that the consumers most at risk of losing continuity of 911 communications during commercial power outages are those in the midst of transitioning from legacy copper, or that are new to non-copper media, because they may currently assume they will be able to reach 911 during a power outage. For example, Public Knowledge asserts that “the new technologies with which AT&T and Verizon propose to replace traditional POTS are not self-powered, do not work with vital devices on which consumers rely, and are not available in every community.” Public Knowledge further argues that, “[w]hile technology transitions hold tremendous promise for a state-of-the-art communications network, the loss of guaranteed backup power or shifting backup power responsibility to the consumer are serious changes that could end up creating a network that serves some and not others.”

17. We agree with the commenters who assert that transitions to new technology should not result in 911 service being more vulnerable than when consumers used the legacy network. As we stated in the *NPRM*, the absence of line powering for some voice services (such as those provided by cable companies) was not an issue that needed to be addressed when legacy line-powered network options were widely available, but it must be addressed as more and more residential subscribers are faced with only VoIP and other residential IP-based services (or legacy services delivered over fiber) as options, because these services typically will require a backup power source to function during power outages. Accordingly, we focus our requirements to support the continued transmission of 911 communications for service that will no longer have line powering capabilities. Because of the importance of the continuity of 911 communications, we also include under the new requirement providers that may have never provided line powering, but that provide services intended to replace traditional POTS services on which consumers have relied for continuous access. With the accelerating transition to new technologies, consumers of these services will no longer have competitive alternatives

that come with line-powering capabilities.

18. We reiterate our observation in the *NPRM* that adequate and reliable access to 911 services and functionalities during emergency conditions is a long-standing public policy objective. Although we recognize that we are in the midst of sweeping change, we believe that voice communications continue to play an essential and central role in the delivery of public safety services, and that this role does not diminish during events that cause power outages. Indeed, it is at these times that consumers most need to know that they will be able to use their home telephone to get help through 911.

19. We recognize that, as noted by some commenters, many users of interconnected VoIP service may well be unconcerned about backup power, choosing instead to rely on their mobile phones or alternative backup sources. Nonetheless, because of the critical nature of 911 communications, we are not persuaded by the argument that there is no need for action to ensure the continuity of 911 communications to homes across the country. Nor are we convinced that we should abandon this effort because of claims that consumer expectations, which have developed over decades, are already reset such that they no longer expect their home phone to work during power outages. Consumers who have yet to abandon (or who have only recently abandoned) line-powered service may not have had their expectations “reset.” At this time of transition, it is these consumers who are more likely to mistakenly believe that they can access emergency services during a power outage when the line power option had already been eliminated.

20. We find merit in NASUCA’s argument that the public interest requires the industry to be responsible for ensuring that its subscribers at least have some option to purchase backup power, either from the service provider or a third party. Therefore, as more fully discussed below, we conclude that the public interest would be best served by ensuring the option for continued access to backup power to maintain continuity of 911 communications during a loss of commercial power.

21. We have previously recognized that the benefits associated with reliable 911 service are substantial. The provision of backup power for network equipment at the subscriber premises promotes the “safety of life and property through the use of wire and radio communication,” by enabling 911 calls for subscribers of the covered services, when the power is out. Specifically, the

rules we adopt today will preserve safety of life by enabling the use of VoIP and other non-line powered services to contact 911 in a commercial power outage, which is what millions of Americans have come to expect from their “home phone.” We expect that providing the option for at least 8 hours of backup power would ensure the ability to make many life-saving 911 calls during commercial power outages. Therefore, we find, as we have before, that “[r]eliable 911 service provides public safety benefits that, while sometimes difficult to quantify, are enormously valuable to individual callers and to the nation as a whole.”

22. We have also previously found that greater access to 911 enables other public safety-related benefits as well. The Commission’s “Text-to-911” proceeding concluded that increasing access to 911 “could yield other benefits, such as reduced property losses and increased probability of apprehending criminal suspects. Also, the increased ability to place 911 calls necessarily means that there is an increased ability to receive calls in an emergency, including calls from public entities attempting to disseminate important information during widespread emergencies (such as evacuation notices). Many communities have installed such a function that “has proven to be effective in other counties and cities, such as San Diego during the fires of 2007.”

B. Covered Services

23. In the *NPRM*, we sought comment to help identify the most essential communications services that a customer would need to get emergency help during a power outage. We referred to this in the *NPRM* as “minimally essential” communications. We intended to afford sufficient power for minimally essential communications, including and especially 911 calls and the receipt of emergency alerts and warnings.

24. We also noted that voice services historically have been the primary means of contacting 911 for emergency help. Moreover, we observed that line-powered service can operate continuously and indefinitely during a commercial power failure, and does not require a backup power source to maintain continuity of communications for access to 911. Thus, we proposed that any rules apply “to facilities-based, fixed voice services, such as interconnected VoIP, that are not line-powered by the provider.”

25. Consistent with this proposal, we conclude that it would be in the best interest of the public to apply our rules

to facilities-based, fixed voice services, such as interconnected VoIP, that are not line-powered by the provider. Our conclusion is based on the fact that, as we stated in the *NPRM*, voice service is still the primary means of reaching help through 911. We clarify that a wireless voice service is “fixed” for purposes of our rules if it is marketed as a replacement for line-powered telephone service and is intended primarily for use at a fixed location. We further clarify that whether a wireless service is “fixed” does not depend on the regulatory classification of the service under Federal or state law, or on the mobile capabilities of the service. Similarly, the use of a femtocell or similar equipment in a residential setting does not automatically convert a mobile service into a fixed service. The decisive factor is whether the service is intended to function as or substitute for a “fixed” voice service.

26. Although the rule we adopt today would allow for calls other than to or from 911, we find there is not currently a means to prioritize the provision of power for only some voice calls (such as 911 calls) over other communications (such as calls to friends and family). Many commenters generally agree that there is no practical way to maintain power for only some calls. For example, according to Verizon, calibrating a provider’s battery backup obligations and capabilities based upon essential versus non-essential calls would be inconsistent with consumer’s expectations, and unnecessarily complex. ITTA, the Alarm Industry Communications Committee (AICC), NASUCA, and others argue that it would be technically difficult, if not impossible, to distinguish among certain types of calls or functions in a way that would allow rapid load-shedding of non-essential communications to conserve backup power, if minimally essential communications were defined as only 911 or emergency communications.

27. Some commenters argue for an even broader definition of covered services, citing various examples. Although we recognize that limiting the definition as we have done omits some services on which consumers currently rely in emergencies, we expect that both the consumer backup power needs and our rules will evolve. More importantly, we do not more broadly define covered services because we find that at this time it would be in the best interests of the public to limit application of our rules to discharge our statutory duty to ensure the continued viability of 911. Imposing specific obligations on providers to support other

communications could introduce confusion and impose costs on providers that may well exceed the incremental benefits. This is particularly true given the many backup power solutions on the market today that are capable of supporting both essential and non-essential communications.

28. We reject the argument of NCTA and others that adopting backup power rules exclusively for fixed services unduly favors competing mobile services. The rules we adopt herein are intended to clarify the obligations of providers and the expectations of consumers in the provision of services that a customer would perceive as replacing line-powered telephone service. Mobile wireless services increasingly compete with fixed services, but they function differently in multiple respects. Perhaps most significantly, mobile wireless devices are battery-powered in their normal mode of operation. Thus, we do not believe that consumers would reasonably expect such devices to draw line power during a commercial power failure. Moreover, the battery that powers a mobile device provides an inherent source of “backup power” that is often capable of providing far more than 8 hours of service per charge, and often may be charged through additional means, such as a car charger.

29. Therefore, we conclude that, at this time, the appropriate services that should be subject to backup power requirements for effective 911 service during power outages are facilities-based, fixed voice service that is not line-powered by the providers, and is offered as a residential service.

C. Responsibilities of Providers of Covered Services

30. To promote clear expectations and customer choice, we adopt a combination of performance and disclosure requirements to empower consumers to understand the backup power options available to maintain continuity of 911 service and to obtain the equipment necessary to provide such service, if they wish, at the point of sale. Providers of covered services must offer at least one technical solution capable of supporting at least 8 hours of uninterrupted 911 service and install such equipment, at the subscriber’s option and expense, as part its installation of service. Within three years, providers of covered services also must offer new subscribers at the point of sale and install, at the subscriber’s option and expense, a 24-hour backup power solution if a subscriber desires additional protection. We also adopt a

disclosure requirement designed to ensure that both current and new subscribers understand their options with respect to backup power and are aware of the consequences of their decisions whether, and to what extent, to purchase backup power. Finally, we encourage providers of covered services to engage in targeted outreach to the communities they serve to ensure that local emergency managers are aware of the limitations inherent in various fixed, residential voice service technologies commonly used in their areas, as well as backup power options for individuals and communities more broadly to maintain continuity of communications in an emergency.

1. Performance Requirements

a. Duration

31. We adopt backup power requirements that offer consumers meaningful alternatives to address their individualized needs, recognizing that consumers may have different preferences for backup power. Comments in response to the *NPRM* confirm that “a one-size fits all solution is inappropriate and would disserve customer interests.” Accordingly, we adopt a phased-in approach that will provide consumers with multiple options. As an initial baseline, we will require providers of covered services to offer, at the point of sale, to install a technical solution capable of supporting at least 8 hours of uninterrupted 911 service during a power outage. Within three years, providers must also offer, at the point of sale, a technical solution capable of supporting 24 hours of uninterrupted 911 service if the subscriber desires additional backup power. To minimize costs and provide flexibility, we do not specify the means by which providers of covered services offer to supply these amounts of backup power; instead, providers are free to develop individual technical solutions. To plan for longer power outages, we strongly encourage providers to inform subscribers of options to extend such uninterrupted service over multiple days and direct subscribers to sources of known compatible accessories such as home, car, or solar chargers. For longer power outages, we do not require providers to offer or install any particular solution, but we strongly encourage providers to inform subscribers at the point of sale, and through annual disclosures to existing and new subscribers discussed below, about known options to ensure uninterrupted 911 service and provide examples of retail sources for associated equipment, which may include third-

party vendor sources if providers do not offer such equipment themselves.

32. In the *NPRM*, we observed that 8 hours of backup power for network equipment at the subscriber premises appears to be consistent with a number of VoIP deployment models already in practice, though some providers have deployed backup power capabilities for up to 24 hours. We find that 8 hours of backup power is the appropriate amount of time to afford consumers with continuity of power in the critical hours immediately after a power outage, and is a backup power duration that is technically feasible today. The record reflects that the option to receive 8 hours of backup power is already an industry norm, as well as a reasonable baseline for the amount of standby time that is likely to be useful to consumers during emergencies. The United States Telecom Association (US Telecom), for example, states that “provisioning eight hours of backup power is consistent with industry standards and reflects what VoIP providers currently employ.” Verizon offers subscribers a 12-volt battery that provides up to 8 hours of backup for voice services and also observes that “[c]ompanies such as Comcast, Cablevision, and Cox offer a battery with eight hours of backup, and Time Warner offers a battery with a choice of eight or twelve hours.” The Electronic Security Association (ESA) and the Alarm Industry Communications Committee (AICC) urge the Commission to promote adherence to the National Fire Protection Association (NFPA) minimum standard on battery backup, which also is 8 hours. In light of this broad consensus, and based on the fact that 8 hours of backup power is already being provisioned today by some providers, we disagree with commenters who suggest that 8 hours is not an appropriate standard for backup power offerings. We find that it is technically feasible for providers of covered services to offer subscribers the option of at least 8 hours of backup power through provider-supplied backup power equipment or by offering compatible third-party equipment. While many providers already offer their subscribers an 8-hour backup power capability, the rule we adopt today establishes a common baseline that will ensure that consumers have access to backup power options regardless of their provider. This will promote public safety and emergency preparedness by allowing subscribers to reach 911 and receive telephone-based alerts and warnings in the critical hours immediately following a commercial

power failure. We emphasize that the requirements we adopt today do not place any obligation on the consumer to purchase backup power; the obligation is placed on the provider not providing line-powered service, to make backup power available to the consumer, and to install appropriate backup power upon initial installation of service if requested by the consumer. To that end, we expect that installers should be able to answer questions about backup power.

33. While we believe that 8 hours of backup power would address the need for continuity of communications immediately after a power outage, we recognize that, in some cases, 8 hours of backup power may not be enough for subscribers to reach critical emergency services during an extended loss of power. AARP urges the Commission to require providers to be “responsible for the deployment and maintenance of voice-enabling CPE that delivers at least 12 hours of standby time.” NASUCA and the Communications Workers of America (CWA) also suggest that a longer time period, such as 12 or 24 hours, would be more useful for subscribers who need a longer duration to attend to other time sensitive matters that arise during the course of a natural disaster or other emergency. While industry commenters oppose a mandate to provide more than 8 hours of backup power to every subscriber, service providers note existing solutions, as well as innovative new solutions, that are capable of supporting longer standby times. Along similar lines, NASUCA urges the Commission to monitor advances in battery technology, and as soon as such technology is available at a reasonable cost, to require providers to furnish backup batteries with 7-day standby time and 24-hour talk time.

34. In light of the critical need for maintaining 911 service during more severe and long-lasting power failures, we will require providers to offer subscribers a 24-hour backup power solution within three years. The record indicates that the provision of 24 hours of backup power is at least technically feasible today. ACA has “determined that batteries with 24 hour stand by capability can be ordered from at least one vendor but are not immediately available because they are not widely used.” As explained below, we do not require providers to offer technologically distinct 8-hour and 24-hour solutions, so a 24-hour solution could consist simply of three 8-hour batteries. Many providers that offer an 8-hour solution are therefore likely to be capable of offering a 24-hour solution with minimal additional difficulty. That said, we want to encourage continued

innovation in the development of 24-hour and longer term backup power solutions and avoid locking in solutions that are minimally compliant but that may not provide the best value to consumers. We will therefore phase-in the 24-hour requirement over three years, during which time we expect providers to work diligently to implement innovative solutions for providing at least 24 hours of backup power that improve upon current offerings in terms of cost, reliability and ease of use. This is consistent with ACA’s recommendation for a phase-in of the 24-hour battery requirement for smaller providers; however, we find that given the overall market conditions for 24-hour battery supplies, including questions about immediate availability, it is appropriate to phase in the requirements for all providers, regardless of size. While NASUCA recommends that the Commission monitor battery backup power developments and phase in the requirements as soon as the market will allow, we find that providing a date certain both allows the market sufficient time to develop, and places a backstop for development, thereby spurring innovation in a reasonable timeframe. In the meantime, we encourage but do not require providers to offer a 24-hour solution using available technologies.

35. As commenters note, the need for continued access to 911 during an extended power outage does not end after 8, or even 24, hours. For example, Public Knowledge argues that “a minimum time of seven days backup power is a reasonable requirement that will keep consumers safe before, during, and after a natural disaster, and allow them to rebuild their communities.” Based on a study by the Environmental and Energy Study Institute, Public Knowledge observes that restoring power after Hurricane Sandy and Hurricane Katrina took 12 and 15 days respectively, and on average takes 7 to 23 days. To address such extended losses of commercial power Public Knowledge asserts that “carriers must prioritize the adoption of devices that use batteries that can last days and are not proprietary.” Other commenters argue that “Americans have come to trust and expect basic telephone service to work indefinitely, particularly during power outages caused by natural disasters and public safety emergencies” and urge us to adopt even longer backup power requirements, ranging from seven days to two weeks.

36. We are not persuaded that a requirement for providers of covered services to offer or install more than 24 hours of backup power is necessary at

this time. All things equal, we would prefer access to 911 during a loss of commercial power to last indefinitely, as consumers have come to expect with line-powered services. We recognize, however, that there are technical, operational, and cost considerations that must be balanced against this theoretical desire. For reasons discussed above, we believe that it is both technically feasible and consistent with current business models for covered services to require providers to offer options for 8 and 24 hours of backup power on the timelines specified in our rules. We agree, however, with commenters who suggest that a mandate to offer backup power for multi-day outages could impose unnecessary burdens on service providers and excessive costs on consumers for comparatively little public safety benefit. As CSRIC has observed, backup power technologies are evolving, and the cost of more advanced batteries such as lithium-ion cells is likely to decrease over time as other options such as power-over-Ethernet become more widespread. We will continue to monitor these developments to ensure that our rules keep pace. Moreover, power outages of extended duration allow well-informed consumers time to recharge their existing batteries or make other arrangements to reach emergency assistance until power is restored. We therefore strongly encourage providers to inform subscribers, both at the point of sale and annually thereafter, of known ways consumers can maintain connectivity during extended power outages. As an example, this could include guidance on restocking or recharging a power supply used to provide 8- or 24-hour capability. Providers could also give information on purchasing other accessories such as solar, home or car chargers that may allow exhausted batteries to be recharged and that are compatible with the provider's equipment. Providers need not offer such accessories themselves or endorse particular third-party suppliers, but they should provide sufficient information, including technical specifications when necessary, for subscribers to obtain compatible accessories from commercial sources. Such information may be provided through welcome kits, brochures, emails to subscribers, or any other means reasonably calculated to reach each subscriber, as discussed below, while providing due consideration for any preference expressed by the customer. Providers sometimes deploy mobile charging stations to areas affected by an extended outage, and may inform

subscribers when such mobile charging stations are made available.

37. In adopting these requirements, we acknowledge observations that “[n]otwithstanding the availability of backup batteries, many customers today choose not to obtain a battery, given the growing reliance on wireless or the customers’ use of handsets or other devices that themselves require commercial power to operate.” We also agree with commenters such as Verizon that “[c]ustomers should be free to decline [a backup] battery, depending on their personal preference.” We further acknowledge that comments in the record indicate that, when it is offered, consumers often may not choose to avail themselves of options to purchase backup power. Commenters note, for example, that many subscribers of fixed, residential VoIP service also purchase mobile voice service that provides an alternate means of reaching 911 in an emergency, and that others prefer cordless phones that require backup power beyond that supplied by service provider networks. Nevertheless, some consumers—particularly the elderly and other populations that are at the greatest risk during an emergency—may not subscribe to mobile wireless service and may rely solely on the continued functionality of their residential voice service to reach 911. Furthermore, mobile networks are not designed in the same manner as wireline networks and may become overloaded in times of extreme use in an emergency situation, and thus be unavailable for use to reach 911. We emphasize that nothing in our rules forces consumers to purchase backup power they do not want. We require only that consumers who want service that will work during power outages and have not otherwise provided for such uninterrupted service have the option of obtaining that capability, and that they have sufficient information to make an informed decision.

38. In the *NPRM*, we discussed the duration of backup power in terms of “the availability of standby backup power, not actual talk time.” Commenters differ on whether backup power should be measured in terms of standby time, talk time, or some other metric that takes into account variations in battery life under different conditions. NASUCA, for example, questions provider assertions about backup battery life on the grounds that 8 hours of battery life yields far less actual talk time, and because batteries deteriorate as they age. Public Knowledge observes that the actual duration of a battery depends on its use, and that the more calls are placed, the

more quickly backup power is depleted. In light of these potential discrepancies, we believe that adopting a uniform definition of “backup power” is necessary to avoid potential consumer confusion. Therefore, we base our backup power requirements on the amount of time a technical solution can maintain a covered service in standby mode, *i.e.*, able to provide a dial tone and to initiate and receive voice calls, but not necessarily in continuous use. We believe that standby time is an appropriate metric, because our rules are premised on the need for covered services to be available to dial 911 or receive incoming communications such as emergency alerts and warnings during emergencies, not necessarily on the need for extended talk time when commercial power fails. We recognize that actual battery life may vary depending on how often subscribers place calls and how long such calls last, but we conclude it would not be practical to account for such situation-specific variations in our rules and that standby time is a more consistent and useful point of comparison. Accordingly, we require providers of covered services to offer subscribers the option to obtain backup power for 8 hours (effective 120 days after publication of this *Report and Order* in the **Federal Register**) or 24 hours (effective within three years thereafter) of standby time, measured at rated specifications, without a duration requirement for actual talk time.

b. Methods of Provisioning Backup Power

39. We agree with commenters who advocate flexibility in how providers achieve continuity of 911 access for the time periods discussed above. The record reflects that providers currently employ a variety of backup power technologies and that a range of backup power options are also available direct-to-consumer from third-party sources. CSRIC, for example, identifies nine “use cases” for residential VoIP deployment, with a range of equipment functioning as an analog telephone adaptor (ATA) with varying levels of battery backup. CSRIC observes that “[t]he most commonly deployed model for VoIP services in the United States is to locate the ATA function in a network device, installed inside the living unit.” In addition, as NCTA states, uninterruptible power supplies (UPS) that can power multiple devices during a power outage are already widely available at national retailers. Bright House also describes “numerous retail options available to subscribers like UPS, portable power packs, solar, and

manual cranks that power multiple devices during an outage and offer a more compelling and flexible solution to subscribers at comparable prices” Some parties also comment that subscribers who use more versatile power options such as UPS should not have to also pay for the duplicative cost of an additional limited-function battery; nor should the Commission require consumers to pay for a backup power option that does not work in their situation.

40. We do not require use of a specific technical solution or combination of solutions. Providers, which are not providing line-powered service, have flexibility to develop and offer their own backup power solutions, as long as those solutions comply with the rules we adopt today. In addition, we expect that installers should be able to answer questions about backup power. For example, a provider could offer a solution with a single, internal battery delivering 8 hours of backup power. With respect to the 24-hour option required within three years, providers may choose to offer consumers a single 24-hour battery (or battery tray as offered by Verizon), three 8-hour batteries, or some other combination of installed and spare batteries. UPS systems or other technologies to provide 24 hours total. If the solution requires a proprietary battery or other equipment that is not widely available in retail stores, the equipment should be provided as part of the installation of service. If, however, the solution accepts commonly available equipment such as D-Cell batteries, providers need not supply such equipment themselves, as long as they notify subscribers at the point of sale that it is not included and must be supplied by the subscriber for the solution to function properly. In cases involving spare batteries that are not widely available at retail stores, the solution offered to subscribers should also include a charger or some other method of ensuring that such batteries are stored in a charged state.

c. Battery Monitoring and Maintenance

41. In the *NPRM*, we sought comment on whether the provider should have any responsibility to monitor backup power status to determine whether the battery had degraded run time or performance. Generally, the comments of individual consumers and consumer advocacy organizations support requiring providers either to maintain and monitor the backup power or to provide subscribers with the means to do such monitoring. For example, AARP urges the Commission to adopt as a rule the CSRIC recommendation that service

providers work with their vendors to provide a mechanism to monitor battery status, and determine whether the battery is degraded. AARP states that this can be done through remote monitoring of batteries as part of the service offered to subscribers, or through LEDs visible to subscribers. Other commenters suggest that the backup power system contain a self-monitoring feature that notifies subscribers audibly and visually when the backup power system is in use, and when it is running low. ESA notes, however, that some subscribers may not pay attention to these warnings, and that it may require personal interaction with subscribers to assist with upgrading or changing a battery that needs attention. On the other hand, service providers generally argue that requiring remote monitoring of backup power is either impractical with current technology or, even if technically feasible, of limited use to subscribers or providers. AT&T contends that “IP-based voice service providers generally do not assume responsibility for monitoring their customers’ backup batteries,” and that “[r]elying on customers, rather than service providers, to monitor and maintain battery backup power for network equipment at the subscriber premises makes eminent sense given technological and marketplace changes.”

42. We do not believe it would serve the public interest to require providers of covered services to remotely monitor backup power status at this time. Similarly, we decline to adopt any requirement that providers inspect or test backup power equipment after fulfilling their initial responsibility under our rules to offer subscribers the option, at the point of sale, for backup power to be installed as part of the initiation of service. This is consistent with CSRIC’s observations that “[i]ncreasingly, battery backup is being offered as an optional accessory to the consumer, which they can control and manage themselves.” While we believe service providers are in the best position to identify and make available backup power solutions compatible with and appropriately sized for specific covered services, we agree with commenters who believe subscribers are in the best position to monitor backup power once installed, and in light of the disclosure requirements we are implementing designed to ensure they are adequately informed on how to do so. With respect to batteries, we are not persuaded that battery monitoring technology has evolved to the point of allowing service

providers to conduct useful remote monitoring of battery status without raising costs to consumers or diverting resources away from more important network reliability issues through an increase in false failure alarms. We observe, however, that our allocation of monitoring responsibility to consumers is based on the expectation that service providers offer adequate information for subscribers to understand when their equipment is functioning properly and when it may require maintenance or replacement. Service providers should also inform subscribers of the potential for batteries to degrade over time and either make replacement batteries available for self-installation at the subscriber’s expense or provide sufficient information for subscribers to obtain replacement batteries from third parties.

d. No Obligation to Retrofit

43. Some service providers express concerns about the cost and complexity of any obligation to retrofit currently installed equipment to comply with any backup power requirements the Commission adopts. AT&T, for example, states that “[i]f service providers were required to provide CPE backup power, the Commission should require only prospective implementation in order to avoid the technological pitfalls of retrofitting prior deployments.” ITTA argues that “[r]etrofitting existing service deployments for customers who are not interested in battery backup power would divert resources from new deployments, thus slowing the expansion of services to customers who desire advanced broadband capabilities.” We agree and decline to adopt any obligation that providers of covered services retrofit currently-deployed equipment to accommodate the amount of backup power specified in our rules for new installations. The record reflects that some covered services are currently deployed without backup power and that consumers may prefer to continue using their existing equipment. Accordingly, we require only that backup power options be offered at the point of sale. Providers may continue offering retrofit options for backup power upgrades to existing customers or those who decline the option at the point of sale, but they are under no obligation to do so. We note, however, that even service providers that do not currently offer backup power acknowledge that third-party UPS units may allow subscribers to maintain communications capabilities without the need to retrofit existing equipment. Therefore, we conclude that providers’ obligations to current subscribers

should include the disclosure requirements discussed below and the option for subscribers to self-install commercially available backup power solutions that are compatible with existing equipment.

e. Compensation and Costs for Providing Backup Power

44. In the *NPRM*, we proposed that any requirement for service providers to ensure a substitute for line power would be premised on the condition that such providers “would be entitled to commercially reasonable compensation in exchange for providing this service.” In response, Public Knowledge asserts that the Commission should use legacy POTS as a baseline and require providers to furnish backup power without an additional fee because, until the transition to IP-based services, reliability has always been paid for as part of a subscriber’s phone bill, and allowing providers to charge for backup power for the same service via new technology would be a step backward. However, this argument disregards the record evidence that batteries or other potential substitutes for line powering carry a not insignificant additional cost over an entire network, and that it is not unreasonable to permit providers to recoup those additional costs from those subscribers who have need for the additional coverage. We also note that it is current practice among many interconnected VoIP providers to charge an extra fee for batteries or other backup power capabilities, suggesting that the expectations Public Knowledge cites may be changing as consumers increasingly adopt VoIP services. As CSRIC has observed, “[o]ne clear trend across all VoIP use cases is that battery backup is increasingly being offered as an option to the consumer, with the cost and maintenance of the UPS and batteries being the consumer’s responsibility.” Ultimately, we are persuaded that subscribers should not have to pay for backup power they do not want. As discussed above, consumers may desire different amounts of backup power—or none at all—depending on their individual circumstances.

45. Accordingly, we conclude that providers of covered services may charge subscribers for the backup power capabilities provided under our rules, if subscribers wish to purchase such capabilities. We emphasize that we do not specify the rates at which providers of covered services may offer backup power or related accessories, we expect market forces to ensure that backup power is offered at competitive prices. A service provider can receive

compensation for all aspects of implementing the rules we adopt today, including the backup power installation, and costs of equipment and labor, from the consumer that elects to have backup power installed. And we do not preclude service providers from including backup power capabilities without separate charge, if they choose to do so for competitive or other reasons.

46. By requiring only that service providers provision backup power upon subscriber request at point of sale, and at the requesting subscriber’s expense, we have effectively negated the argument that these rules will substantially increase costs to providers. The majority of commenters who raise issues related to costs base their arguments on the assumption that the Commission would mandate a universal backup power solution across all subscribers, including retrofitting existing subscribers. The action we take today will substantially limit the providers’ costs by requiring backup power installations only for customers that request backup power at the point of sale, and at those customers’ expense. Fiber to the Home Council Americas states that “while the industry has generally supplied backup batteries to all subscribers, it would make a material difference to the cost of a build, enabling expansion into less dense areas, if it could supply battery backup only to those subscribers that expressly want it—a number all-fiber service providers has determined is not great.” Similarly, NCTA stated that in their experience only a small number of customers have purchased backup power. We also find concerns about the environmental effects of requiring all consumers to obtain backup power are inapplicable because we do not make such a requirement.

47. There are additional factors that minimize the costs associated with compliance for the covered providers. First, as noted previously, the record indicates that numerous entities comprising a significant share of the IP voice services market are already offering their customers 8 hours of backup power; for those entities no additional costs are necessary. To the extent that a service provider is not currently offering the requisite 8 hours of backup power, the fact that numerous providers are currently offering such a solution indicates that solutions exist and are widely available. Accordingly, there is little need to custom-design a solution when many of the solutions can be used universally. Indeed, providers may avoid the costs of supplying or installing a proprietary

solution. This also saves providers the costs of supplying batteries directly. The same cost-mitigating principles apply to the discussion of 24-hour and extended duration backup power; the commercial market for this solution already exists and even the smaller providers are confident in their ability to provide this level of backup power if provided ample transition. The record also indicates that many providers already offer some form of backup power, even if it is not an 8-hour solution, and therefore would be familiar with the practice of installing backup power solutions for their customers. Because the cost to providers of complying with this rule should be minimal both at the outset as well as when the 24-hour requirement takes effect, and the particular benefit to the public of enhanced continuity of communications to reach help through 911 during power outages is substantial, we conclude that our action today produces a net public benefit.

2. Subscriber Disclosure Obligations

a. Need for Subscriber Disclosure Obligations

48. In the *NPRM*, we sought comment on whether we should require providers to develop and implement consumer education plans regarding the availability of backup power, and noted our belief that such plans “would be critical to consumers’ ability to successfully self-provision.”

49. Commenters representing government stakeholders and consumers support such a requirement. For example, PA PUC states that, if providers require their customers to be responsible for purchasing or replacing backup power batteries, providers “must develop and implement outreach and education programs to ensure customers are aware that [customers] are responsible for providing their own backup power.” The New York Public Service Commission indicates that it is “critical that information about the consumer’s role in maintaining continuity of power is transmitted to the customer by the service provider,” and that providers need to develop programs to “ensure consumers are aware that [they] are responsible for providing their own backup power.” The Attorneys General for the Peoples of the States of Illinois and New York state that, because of the reluctance to advertise a diminished service, “carriers may not emphasize the need for backup power disclosures.” The FCC’s Intergovernmental Advisory Committee asserts that “providers should be required to communicate effectively and accurately the services that may no

longer be available and options for consumers to obtain comparable services, including options with respect to backup power supplies.”

50. Industry stakeholders, on the other hand, oppose such a requirement. The Independent Telephone & Telecommunications Alliance (ITTA) states that there is “no evidence that additional consumer education would be helpful or necessary, and argues that a requirement is “unwarranted and a waste of resources.” AT&T recommends that the Commission refrain from imposing a consumer education requirement, and instead work with providers to review backup power best practices for consumer education. Others, such as CenturyLink, Hawaiian Telcom, NCTA, and Verizon, suggest that the Commission support the implementation of CSRIC recommendations regarding consumer notification. They argue that this would give providers the flexibility to implement consumer education measures as their networks and business models warrant.

51. Others argue that a requirement is unnecessary because providers already give consumers information related to backup power. For example, NCTA argues that the Commission’s existing rules already “ensure that consumers are made aware of the backup power ramifications of choosing a VoIP service,” and require providers at the initiation of interconnected VoIP service to “inform consumers of the ‘circumstances under which E911 service may not be available.’ . . . includ[ing] ‘loss of electrical power.’” ITTA notes that it is “standard industry practice for interconnected VoIP providers to notify consumers regarding the potential limitations of IP-enabled voice services and equipment during a power outage.” Fiber to the Home Council Americas (FTTH Council) also asserts that industry efforts to notify consumers about battery backup availability are effective based on assumptions regarding consumer adoption of wireless and VoIP services.

52. AT&T states that providers of IP-based voice service already educate consumers on the necessity of a backup battery during a power outage and provide information about the backup battery, including practices for prolonging battery life, where to purchase battery replacement, and replacement instructions. CenturyLink indicates that it plans to provide information regarding “sample batteries that would work with [CenturyLink] equipment as well as suppliers of such equipment for those customers wishing to provide their own backup power.”

Charter and Cablevision state that they are making “significant efforts to educate their customers about the VoIP services they offer, including that such service will not work during a power outage without a backup battery.”

53. We find that the lack of uniformity in providers’ backup power information, and as commenters present, lack of consumer awareness at a time of technological transition, may lead to consumer confusion about consumer expectations and responsibilities in the access of 911 service during power outages. While some providers already offer or plan to make available information to consumers in the near future, it appears from comments submitted and providers’ Web sites that the information provided to consumers is not consistent across the industry. This lack of uniformity may lead to consumer confusion at a time of technological transition from services provided over copper networks to services provided over IP-based networks, and agree with commenters that there are consumers who “may not be aware that VoIP and wireless service operate differently from traditional landline telephony in a commercial power outage.” We acknowledge the concerns of commenters representing unique populations, such as AARP, which states that “[g]iven the diversity of service provider practices . . . the level of consumer understanding of CPE battery backup issues is certainly not uniform.” Further, subscriber complaints reveal that current disclosure practices are likely insufficient. For example, the Commission’s consumer complaints portal reveals that some subscribers are frustrated by VoIP service providers’ failure to inform subscribers about the need to self-provision a battery to operate backup power in order to access 911 services. Based on the record, while we acknowledge that there are some disclosures already mandated and some additional information provided voluntarily, we are not convinced disclosures currently required only for interconnected VoIP providers, are of sufficient scope or uniformity across all covered providers, to satisfy the Commission’s obligation to promote the safety of life and property and ensure consistent 911 services. Although not all subscribers may receive backup power information from more than one provider in a given year, we acknowledge that backup power information may be confusing especially for unique populations struggling during the technology transition, or those who may need to switch providers

often, such as military families needing to relocate. We find that it is in the public interest for the Commission to establish a uniform requirement to provide minimum information as described below in order to ensure that all subscribers of covered services are equipped with necessary information to access 911 services during power outages regardless of provider or technology used.

54. Adoption of best practices established by CSRIC, as recommended by some industry commenters, may help, and we do not intend to discourage adoption of these practices. However, we are not convinced that the voluntary adoption of these practices without a standard, mandatory baseline will eliminate consumer confusion. We therefore address these concerns by requiring minimum subscriber disclosure obligations, while at the same time encouraging providers to voluntarily follow additional CSRIC best practices regarding backup power.

55. As NCTA discussed, current Commission rules require a limited customer notification for interconnected VoIP service providers. This requirement, however, is only for a subset of covered providers considered in this *Report and Order*, and we find that the information currently required is too limited to fully inform consumers about backup power. Specifically, section 9.5(e)(1) of the Commission rules requires customer notifications for circumstances such as “loss of electrical power,” “under which E911 service may not be available through the interconnected VoIP service or may be in some way limited by comparison to traditional E911 service.” Informing consumers of the circumstances under which their E911 service is not available does not adequately inform a consumer on how to purchase, efficiently use, monitor, or replace backup power at the consumer’s premises.

56. We conclude that requiring providers to develop and implement subscriber disclosures regarding backup power with minimum baseline disclosures serves the public interest and will promote access to 911 while being of minimal cost to the providers. As CenturyLink notes, there is a clear public benefit in promoting consumers’ awareness of the need for affirmative action to acquire and maintain backup power. According to the Communications Workers of America (CWA), “Commission oversight is essential to encourage . . . consumer education about the time limits and capabilities of battery-provided backup power.” Attorneys General state that “enabling consumers to prepare

themselves for emergencies and avoiding public confusion should be fundamental Commission goals.” We agree with these commenters, and others, who recognize the importance of consumer information in managing the historical consumer expectations regarding continuity of communications. As described in detail below, we also find the costs to providers in making the required disclosure to be minimal.

b. Minimum Information Elements

57. The disclosure requirements adopted today are intended to equip subscribers with necessary information to purchase and maintain a source of backup power to enhance their ability to maintain access to reliable 911 service from their homes. Several parties commented on what information should be included in the disclosures. For example, some commenters strongly support including information about battery life spans, procedures for ordering, installing, replacing, and extending battery life during a power outage. The City of New York recommends that we require providers to furnish information to assist in extending the “useful life of battery backup” such as powering off the system or closing applications. APCO suggests that a public education requirement include information on “any impact to 9–1–1 services.” The respective Attorneys General for the State of Illinois and the State of New York strongly support consumer education addressing the many factors that can affect the amount of “stand-by time” a backup power solution provides. The California PUC urges the Commission “to mandate that service providers give customers educational materials consistent with California’s existing requirements,” which include, for example, requiring providers to tell their customers that their services require backup power on the customer’s premises, limitations of service, and potential service failure during power outages. The California PUC also requires providers to tell consumers about how to best “maximize the ability to make or receive necessary phone calls during an outage.”

58. In addition to commenting on the appropriate level of disclosure in any Commission requirements, some commented on the opportunity for states to require more extensive disclosure. For example, the California PUC requests that the Commission allow the states to “adopt more extensive backup power requirements.” Similarly, NARUC suggested that the Commission establish “a floor” that

does not impact more protective state-level measures.

59. Several industry commenters identified information that is currently included in some backup power notifications to subscribers. For example, ACA asserts that providers inform potential and current subscribers that their voice service is not powered by the network, and during a power outage, without battery backup, the subscriber may lose access to 911. ACA explains that this notice also alerts customers about specific backup power capabilities of the equipment.

60. We agree with the commenters who suggest that the Commission adopt minimal requirements for the types of information that service providers must give subscribers, regarding backup power. This will decrease the likelihood of consumer confusion, and ensure that all subscribers have access to basic information about the need for, and how to acquire and conserve, backup power. In this respect, we observe that several providers already give relevant information to their customers; however, the amount and type of information given varies greatly from one provider to another, and thus gives rise to the potential for consumer confusion. This confusion may lead the consumer to fail to take proper precautions to acquire and maintain backup power, and ultimately result in the inability to access 911 at a critical moment during a power outage. Thus, we find it in the public interest to identify minimum information that must be communicated to consumers regarding backup power. In this respect, we require providers to disclose to subscribers the following information: (1) Availability of backup power sources; (2) service limitations with and without backup power during a power outage; (3) purchase and replacement options; (4) expected backup power duration; (5) proper usage and storage conditions for the backup power source; (6) subscriber backup power self-testing and monitoring instructions; and (7) backup power warranty details, if any. In order to minimize the burden on smaller providers, we direct the PSHSB to work with CGB to develop such forms or other documents, prior to the implementation date of these rules for smaller providers, as herein defined, for the use of smaller providers in disclosing the required notifications to their subscribers, including subscribers with disabilities.

61. *Availability of Backup Power Sources.* Subscribers must be made aware whether their service is capable of accepting backup power and, after the initiation of service, whether they may

obtain backup power from the provider or from a third party. Some providers post this information online, but we find that the posted information is both too limited and not readily accessible by all subscribers. Therefore, it is insufficient notice to subscribers of a critical piece of information that they need to ensure continuity of access to critical 911 services during a power outage. Accordingly, we require providers to inform new and existing subscribers about the availability of compatible backup power sources for their service, as outlined below. Again, we emphasize that providers are not required to research and/or provide information on every possible backup power source that could potentially be compatible with a Covered Service; disclosure obligations under our rules are limited to basic information allowing consumers to make informed choices about their purchase and use of backup power to maintain continuity of access to 911.

62. *Service Limitations With and Without Backup Power.* We require providers of Covered Service to notify subscribers about the service limitations with and without the use of a backup power source. As we stated in the *NPRM*, consumers of wireline telephony may expect their plug-in phones to work during a power outage without any further action on their part. Non-copper based networks and services not based on TDM may not support these traditional wireline functionalities, or may not support them in the ways consumers have come to expect. We are persuaded by commenters who support more fulsome disclosures of service limitations. Accordingly, we require providers of Covered Service to inform subscribers about the impact of power outages on the use of 911 services and the type of service that will continue to work with backup power. For example, the obligation may be satisfied by notifying subscribers that voice service will be unavailable during a power outage without backup power, and that this backup power will not also power services other than voice. Further, to the extent the provider has information about other services at the subscriber premises—for example, home security, medical monitoring devices, or other similar equipment—the provider should notify the subscriber that these services will not be powered by the backup power source for voice service.

63. At this time, we decline to require providers of a Covered Service to disclose the limitations of cordless handsets during power outages. Commenters such as US Telecom and California PUC note that cordless

phones rely on commercial power, and will not function during a power outage. Accordingly, the California PUC supports a requirement that providers tell consumers that “cordless phones will not work in power outage.” However, we observe that the concern about cordless phones not functioning during a power outage exists regardless of the underlying network providing service to a subscriber; that is, it is an equipment issue that does not depend on the type of underlying network—copper, fiber, or cable. Accordingly, we do not believe it is imperative to impose such an obligation here on the service provider.

64. *Purchasing and Replacement Options.* Providers of Covered Service must inform subscribers about backup power purchasing and replacement options to enable subscribers to make informed decisions regarding whether to purchase backup power and how to find backup power that is compatible with the service. If, after the initiation of service, the provider does not sell a backup power source directly to subscribers, the provider must give subscribers enough identification information about what type of power source is compatible as well as purchasing options. Such identifying information must, at a minimum, include where to purchase a power source, the approximate cost, and the voltage and type of battery that is compatible with the service. That many providers currently make this information available suggests that the burden of doing so is not unreasonable.

65. *Backup Power Duration.* Providers of Covered Service must inform subscribers about the expected duration of the backup power source and factors that impact duration, e.g., usage and storage conditions. We agree with the commenters who argue that standby time can be affected by many factors. Therefore, in addition to explaining the length of time the provider’s backup power source is expected to power the service in standby mode and, to the extent possible, the expected amount of talk time, providers of Covered Service must notify subscribers of the proper backup power usage and storage conditions, and how these affect the backup power source operation during a power outage. This obligation includes identifying how subscribers may limit and conserve backup power both before and during a power outage. We agree with the suggestion of the City of New York that providers furnish “information to assist the [subscriber] in extending the useful life of battery backup.” Accordingly, providers of Covered Service must advise subscribers

of the proper backup power storage and charging conditions so that subscribers know, for example, whether battery power life, capacity, or run time will decline, whether the batteries must be replaced after a certain amount of time, and the proper storage temperatures. That is, the information provided must at a minimum clearly inform subscribers about the impact of environmental factors.

66. We strongly encourage providers to assist subscribers in developing a plan for extended backup power by notifying them of options to extend backup power beyond the life of the battery. For example, providers could inform subscribers that they could purchase several backup power units for use during prolonged outages, and provide directions for rotating these as required to keep the units charged. We also strongly encourage providers to inform subscribers of any available accessories such as solar or car chargers, which may be able to recharge a depleted backup power unit. And, when applicable, providers should inform subscribers of the availability of deployed mobile charging stations. This information will arm subscribers with the knowledge necessary to be prepared for extended power outages and to take steps to mitigate disruption to their 911 communications.

67. *Testing and Monitoring.* Although we do not require providers to monitor backup power sources, when the subscriber purchases backup power directly from the provider, the provider must inform and instruct subscribers about how to self-monitor and self-test the backup power source. Several commenters support such a requirement, and we find the analogy in the comments of MDTC to be appropriate: “like smoke alarms, IP equipment have similar importance to personal and public safety and is usually dependent upon the user for periodic testing and battery replacement.” We are persuaded by these commenters that providers must clearly explain how a subscriber may test, monitor, and maintain the backup power source. We observe that several providers are currently effectively providing pictorial or other detailed explanations about subscriber self-testing and self-monitoring of backup power. Given their ongoing relationship with their subscribers, we find that providers are in the best position to notify and remind subscribers about how to test and monitor backup power. By furnishing specific instructions to subscribers on how to self-monitor and test backup power sources, providers will decrease consumer confusion, and

greatly enhance the public’s ability to maintain critical communications during power outages.

68. *Warranty.* If the subscriber acquires the backup power from the provider, the provider must explain the elements of the warranty, if any, such as the warranty expiration date, and under what circumstances a replacement would be provided. We note that several providers already effectively offer online information regarding replacement procedures, which suggests that this is information that is helpful to consumers in preserving their ability to reach 911.

c. Availability of Required Information

69. Each element of the information described above must be given to subscribers both at the point of sale and annually thereafter, as described below. This information will help subscribers plan in advance to extend the effectiveness of their backup power and ultimately, as we stated in the *NPRM*, count on the continued availability of 911 service in harsh weather conditions or other emergencies when consumers are most vulnerable.

70. We sought comment in the *NPRM* on when providers should make information available regarding backup power. For example, we asked whether the information should be made available at the point of sale, at the initial set up of service, or at some other point in the process. We also asked whether providers should make detailed backup power information available prior to a predicted extreme weather event or other anticipated emergency.

71. Commenters support disclosure of backup power information to subscribers at various points in time. For example, the Attorneys General argue that the Commission should inform subscribers “when new service requires additional equipment to access emergency services in a power outage.” The CPUC supports providing information upon “service initiation and annually thereafter regarding backup power,” as well as sending “an annual reminder to customers to check the status of their battery.” On the other hand, providers such as CenturyLink see value in asking “at the point-of-sale” if their customers want backup power, at which time consumers will be assessed a “one-time, non-recurring charge.”

72. We are persuaded by comments supporting an initial disclosure at the point of sale for the new service and an annual disclosure for all subscribers, both new and existing. We agree with AT&T that subscribers should have the information they need to “shop among

competitive alternatives for backup power, including the alternative of opting out of backup power altogether.” As commenters note, service providers have an important role in disseminating information to their subscribers. AARP states that the “availability and distribution of accurate information related to CPE backup power from reliable sources is an important means to empower consumers.” Equipped with initial and annual notifications, including the disclosures and information as described above, all subscribers, both new and existing, will be in a better position to make backup power purchase decisions and conduct regular maintenance in order to ensure access to 911 services during power outages.

73. We also sought comment on how providers should make backup power information available to consumers. Commenters suggest that providers should offer information on Web sites, and in individual electronic and paper billing materials. ACA, for example, states that its members use a variety of approaches, such as posting information on the operator’s Web site, to inform subscribers about backup power supplies for CPE. CenturyLink states that “service providers are increasingly communicating with customers about the issue of backup power,” and supplementing brochures provided to customers with information on the company Web site. ESA raises concerns that there may be scenarios, for example with the elderly, requiring “personal interaction with consumers to assist with upgrading or changing a battery.” NTCA, GVNW, and Vantage Point Solutions suggest that consumers that “utilize an assistive device in connection with a disability” should be part of the consumer education process.

74. We seek to provide flexibility regarding the manner in which providers inform their subscribers, while also honoring any preferences expressed by customers. We thus permit providers to convey both the initial and annual disclosures and information described above by any means reasonably calculated to reach the individual subscriber. For example, a provider may meet this obligation through a combination of disclosures via email, an online billing statement, or other digital or electronic means for subscribers that communicate with the provider through these means. For a subscriber that does not communicate with the provider through email and/or online billing statements—such as someone who ordered service on the phone or in a physical store and receives a paper bill by regular mail—

email would not be a means reasonably calculated to reach that subscriber.

75. We observe that many providers use a variety of methods to offer backup power source information on their Web sites as well as in welcome kits, including charts, pictorial explanations, and links to backup power source manufacturers. We encourage providers to continue to do this, as long as required disclosures are reasonably calculated to reach each subscriber. Posting information on a Web site may be helpful but, by itself, would not satisfy our requirement that notifications be reasonably calculated to reach individual subscribers, even for those subscribers that communicate with the provider via online means. Further, we are persuaded by commenters that there are populations, such as the elderly or individuals with disabilities, who have no or a very limited online relationship with the provider or otherwise may need more targeted consumer education outreach beyond posting online information.

76. We believe that the cost of these backup power disclosure requirements will be minimal and, thus, will be exceeded by the significant benefits we expect to result from this subscriber disclosure, such as enhanced subscriber access to 911 services. Among other things, we note that the vast majority of providers already furnish subscribers with some backup power information. As a result of current disclosure practices, we expect that only a small share of the providers will need to take additional steps to comply with these rules beyond modifications to existing disclosures. Similarly, providers already furnish subscribers with information upon initiation of service, and are free to include the information we require herein with the other materials, removing the need for a special cost of distribution. Also, in order to limit costs to providers, we make clear above that a service provider may fulfill its disclosure obligation via any means reasonably calculated to reach the consumer, while also honoring any preference expressed by the customer. Such methods may include electronic outreach, including email notification and paperless billing statements; paper copies are not required for subscribers who access and receive information through those means. The annual notification associated with this requirement gives service providers ample time to plan, for example including the appropriate notifications in normally-distributed billing statements in a manner that does not serve to increase the number of printed pages distributed. As noted above, the

Commission will further reduce compliance costs by providing guidance as to the required notifications to subscribers. Accordingly, the costs of satisfying the notification requirement should be minimal for service providers, and the benefits of informing consumers of backup power solutions in order to reach 911 service from the subscriber premises during power outages, far outweighs any such minimal costs.

77. As with the rules obligating providers to offer backup power solutions, there are numerous benefits associated with the disclosure requirements on how commercial power outages affects VoIP service. Millions of Americans have come to rely on their TDM voice service working during a commercial power outage to call 911. With this backdrop, educating consumers that their phones will not work in a commercial power outage absent backup power is essential even if the consumer opts not to purchase backup power. At a minimum, an educated consumer will not have the expectation of relying on a VoIP service only to have it fail to operate when the consumer tries to make a 911 call, wasting valuable time in the process. In this way the consumer notifications not only promote the availability of 911 service in power outages, pursuant to our statutory mandate governing IP transitions, but also promote the “safety of life and property through the use of wire and radio communication,” the Commission’s statutory charge, by enabling customers to know the limitations of their service in an power outage situation and to make alternate arrangements—either via a backup power solution or alternate means of communication—to ensure the 911 call can go through. This is consistent with our findings with respect to requiring minimum wireless location accuracy where we found that the rules “will improve emergency response times, which, in turn, will improve patient outcomes, and save lives.” We find, therefore, that it is reasonable to expect that the rules we adopt today will save lives and result in numerous other benefits that are less quantifiable but still advance important public interest objectives. Given that the notification requirements contained herein have minimal associated costs, we find that the benefits of these rules far exceed the costs.

3. Community Outreach

78. In the *NPRM*, we sought comment on whether we should require providers to develop and implement consumer education plans regarding the availability of backup power. We also

inquired whether there is a need for measures beyond written notice to customers. The few commenters that addressed this issue see a need for outreach beyond written disclosures to subscribers for the Nation to make the transition to an all-IP environment effectively and with the least amount of consumer confusion. We agree with NASUCA that a backup requirement without a comprehensive consumer education plan would be of limited value, and we find that a truly comprehensive plan should contain an outreach component. That is, as noted by the Massachusetts Department of Telecommunications and Cable (MDTC), written notice to subscribers is only a portion of the consumer outreach and education that is necessary during these times of technology transitions.

79. We agree with MDTC that to provide for flexibility in the delivery of technology transition information, while ensuring its accuracy and effectiveness, providers should develop outreach and education plans in coordination with state, local, and tribal agencies and community organizations. Our Intergovernmental Advisory Committee (IAC) notes that “education efforts must include all levels of governments that interact with consumers. In this manner, state, local and tribal governments will be able to assist consumers in making informed choices that satisfy their communications needs.” However, the IAC further believes that providers instead of the FCC, state, local or tribal governments should have the primary responsibility to do consumer outreach on technology transitions. Thus, the IAC asserts that the FCC should “require [] providers to inform consumers of their options well before actual transition occurs.” For example, the IAC recommends that “providers should have dedicated phone, Web site and email contacts for consumers to report issues, and to obtain information. The objective of such outreach should be to provide information and answer questions, rather than market new services to consumers.”

80. We recognize that many providers already offer consumer education beyond providing mere written notice, and they already engage in community outreach as well. We see great value in providers forging closer relationships with communities, so that local officials can know and understand the likelihood that their residents will be able to summon help, or communicate the status of their welfare in an extended power outage. Community outreach can also help ensure the best possible outcome before disaster strikes (for example, by encouraging communities

to maintain sufficient supplies of batteries and other UPS equipment).

81. We also note that many communities have a robust telephone-based alert capability to warn residents of emergencies in their area. For this reason, and for the great value in being able to receive incoming calls from emergency services personnel, providers of covered services should organize their outreach to subscribers pursuant to this *Report and Order* around the goal of sustaining continuous communications availability.

82. In order to minimize cost and provide maximum flexibility, at this time, we encourage, but do not require, all providers to engage in the type of community outreach that would be required for a consumer education plan to truly be considered comprehensive.

D. Legal Authority

83. Today we adopt rules to educate and empower consumers to take necessary steps to ensure that their “home phone” is capable of making 911 calls during a power outage. These rules are well-grounded in the “broad public safety and 911 authority Congress has granted the FCC.” Congress created the Commission, in part, “for the purpose of promoting safety of life and property through the use of wire and radio communications.” Congress specifically directed the Commission to “designate 911 as the universal emergency telephone number within the United States for reporting an emergency to appropriate authorities and requesting assistance,” in legislation the purpose of which was to “encourage and facilitate the prompt deployment through the United States of a seamless, ubiquitous, and reliable end-to-end infrastructure for communications . . . to meet the Nation’s public safety and other communications needs.” The DC Circuit has also specifically upheld the Commission’s extension to interconnected VoIP providers of the obligation “already required of providers of traditional telephone service [to] transmit 911 calls to a local emergency authority.” In 2008, Congress expressly confirmed that authority to adopt rules that “promote and enhance public safety by facilitating the rapid deployment of IP-enabled 911 and E-911 services.” Congress has also charged the Commission with promulgating “regulations, technical standards, protocols, and procedures as are necessary to achieve reliable, interoperable communication that ensures access by individuals with disabilities to an Internet protocol-enabled emergency network, where achievable and technically feasible.”

84. In this *Report and Order*, we exercise this broad and longstanding authority over 911 to impose requirements on residential facilities-based voice service providers in their provision of 911 service. Our adoption of rules to enable the continued provision of 911 service during power outages—a logical component of the larger duty to provide 911 service in general—lies clearly within this authority. The Commission’s “broad authority” over 911 is grounded in multiple statutory provisions, as discussed above, that work together to promote universal access to 911. The rules we adopt today contribute to the implementation of this statutory scheme by facilitating the provision of 911 service under specific circumstances: when a customer is relying on a residential voice service that is not line-powered to place a 911 call during a power outage. These rules will ensure that customers who may face such circumstances are aware of the limitations of their service and empowered with options for maintaining 911 access in the event of power loss, closing a potential gap in the provision of 911 service. This *Report and Order* further advances the Commission’s statutorily mandated responsibilities over 911 by promoting the availability of 911 service during times when reports of emergencies and requests for assistance may be particularly urgent, as well as by enabling persons with disabilities to maintain 911 access during such periods. The rules will thus help the Commission more effectively implement Congress’s statutory goals of ubiquitous and reliable 911 service for all Americans.

85. Many commenters agree that our adoption of requirements to promote continuity of access to 911 during power outages is an appropriate—and necessary—exercise of our statutory public safety authority. Communications Workers of America states that “[t]he Commission has the statutory obligation to promote public safety through our nation’s communications networks” and affirms our view that “protecting public safety is one of the core principles that must guide [the Commission’s] policies during the technology transition.” The Alarm Industry Communications Committee (AICC) also contends that “[b]ackup power requirements should be adopted to protect consumers and to meet the Commission’s mandate to promote the national defense and the safety of life and property” under Title I. Similarly, the PA PUC “believes that

the [FCC] has the statutory authority to address this issue and require that providers have sufficient backup power to maintain 911/E911 connectivity during commercial power outages so long as the federal rules do not preempt more stringent state rules.” AARP comments that “[w]ith regard to the NPRM’s questions regarding whether the Commission has sufficient authority, the answer is an unequivocal yes.”

86. Commenters also cite the importance of safeguarding 911 service in particular as a basis for our adoption of rules proposed in the *NPRM*. The Electronic Security Association notes that “[n]ot only is standby power for communications important for life safety systems, but it is also critical in allowing the consumer to dial 911 during [power] outages.” AARP similarly observes that “[t]he issue of CPE backup power also overlaps the 911 reliability issue” and suggests that backup power requirements would fill an existing gap because the Commission’s 911 reliability rules “do not address the reliability of access network components that are associated with the origination of 911 calls.”

87. We disagree with Corning’s suggestion that the rules we adopt today contravene the holding of *American Library*. That court’s statement that the Commission’s “general jurisdictional grant does not encompass the regulation of consumer electronics products . . . when those devices are not engaged in the process of radio or wire transmission” is inapposite: the rules we adopt govern the provision of 911 service—which is either “radio or wire transmission”—during power outages. These rules grant providers maximum flexibility to define the technical parameters of backup power solutions they offer to achieve that goal. In the absence of line powering, these solutions may incorporate any number of proprietary and competitively sourced inputs, including D-Cell, lead-acid or lithium-ion batteries, UPS, solar panels, power over Ethernet or other technologies, including combinations thereof, provided that the solution on “offer” can support the required continuity of 911 service during a power failure. This service-oriented requirement is thus far different from the “broadcast flag” rule struck down in *American Library*. The court held that the latter rule impermissibly “impose[d] regulations on devices that receive communications after those communications have occurred” rather than on “communications themselves.” The requirements we adopt are obligations with respect to radio and wire communications. Indeed, the

purpose of these requirements is to promote access to and awareness of solutions that enable 911 calls to be originated during a power outage. The requirements therefore cannot be said to apply “after . . . communications have occurred.” The fact that devices or equipment operating on backup power may remain in standby mode when not in use, or that our performance rule is defined in terms of “standby time,” does not change this analysis. Defining the rule in terms of “standby time” is simply a means of specifying the period of time in which the rule requires 911 service be provided—*e.g.*, during the first 8 hours of an outage. Backup power solutions offered under our rules are not required to meet any performance standards that apply *while* a device is in standby mode, except that the solution must make 911 calling “available” throughout the standby period.

88. For similar reasons, we find unavailing AT&T’s comment that “[b]ecause the Commission has deregulated CPE, it has disclaimed any authority to impose CPE backup power requirements.” The rules we adopt today do not apply to CPE or regulate CPE. Rather, those rules govern the obligations of service providers to provide access to 911 service during a commercial power outage in the absence of line powering. While solutions offered under our flexible performance rule may encompass—solely at such providers’ option—the backup of some devices or equipment that might be classified as deregulated CPE, that does not mean that our rules cannot encompass such equipment when powering such equipment (which is located on a customer’s premises) is part of the solution chosen by the service provider. As discussed above, there is no general requirement to provide backup power for all equipment that might be located at the customer’s premises. Rather, the requirement is that, in lieu of line powering provided as a part of traditional POTS service, a covered service provider must offer a backup power solution that provides the customer with 911 access during a commercial power outage.

89. *First Amendment*. The disclosure obligations we adopt today are permissible under the First Amendment of the U.S. Constitution. No commenter asserts otherwise. In general, government regulation of commercial speech will be found compatible with the First Amendment if it meets the criteria laid out in *Central Hudson*: (1) There is a substantial government interest; (2) the regulation directly advances the substantial government interest; and (3) the proposed regulation

is not more extensive than necessary to serve that interest. As we have noted, the government has a substantial interest, enshrined in Section 1 of the Communications Act, in protecting the safety of the public through the use of wire and radio communications. The Commission has also long observed that “the government has a substantial interest in ensuring that consumers are able to make intelligent and well-informed commercial decisions in an increasingly competitive marketplace.” The disclosures here directly advance that government interest by warning consumers of the potential loss of access to 911 during commercial power failures and informing consumers of backup power options to maintain continuity of such communications. Like the “anti-cramming” rules the Commission adopted in 2012, we conclude that the disclosure requirements adopted here withstand Constitutional scrutiny, in that they advance the substantial government interests of protecting public safety and ensuring that consumers are able to make informed choices about uninterrupted access to 911 through networks that lack line power without requiring any more extensive disclosure than necessary to serve those interests.

90. Moreover, under the standard set forth in *Zauderer*, compelled disclosure of “purely factual and uncontroversial” information is permissible if “reasonably related to the State’s interest in preventing deception of consumers.” Courts have also recognized that other government interests beyond preventing consumer deception—here, the public safety interest in uninterrupted access to 911—may be invoked to sustain a disclosure mandate under *Zauderer*. The information about backup power disclosed to subscribers under our rules consists of factual information regarding the limitations of networks not equipped with line powering, and it is not disputed that this limitation exists or affects the provision of 911 service during power outages. This information plays an important role in preventing consumer confusion by setting clear and consistent expectations about subscribers’ ability to reach 911 in an emergency. It also allows consumers to make informed decisions about the amount and type of backup power they purchase, further reducing consumer confusion and preserving public trust in the 911 system as a means of reaching emergency assistance.

E. Sunset Date

91. The rules we adopt today ensure that consumers are adequately informed

about the role of backup power in the technology transitions and that they have the ability to purchase backup power for their service. Clearly delineating the respective roles of the provider and the consumer during this period of transition minimizes the potential for confusion or for unforeseen lapses in 911 service availability during power outages, and creates baseline expectations. Over time, we expect that both the marketplace and consumer expectations will evolve along with advances in technology so that adequate backup power solutions and availability will become commonplace. In light of this prediction, we will sunset the requirements adopted in this *Report and Order* on September 1, 2025. We anticipate that this ten-year period will allow sufficient time for a “cultural and educational shift” in consumer expectations, along with marketplace and technological development. Consumers will then be empowered to assume primary responsibility over their backup power, similar to the responsibility consumers now bear for mobile devices they may rely on for 911 access during an emergency. If, however, we determine after ten years that the marketplace and expectations have not evolved in the predicted manner we may take appropriate action designed to extend and/or modify the requirements contained herein.

IV. Procedural Matters

A. Final Regulatory Flexibility Act Analysis

92. Pursuant to the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was included in the NPRM in PS Docket No. 14–174. The Commission sought written comment on the proposals in this docket, including comment on the IRFA. This Final Regulatory Flexibility Analysis conforms to the RFA.

B. Paperwork Reduction Act Analysis

93. This document contains new information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements adopted in this *Report and Order*.

94. In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we previously sought

comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees, in the FRFA in Appendix B of the full *Report and Order*, paragraphs 19–23. In this document, we have assessed the effects of the new rules adopted herein on small business concerns and find that the rules adopted here minimize the information collection burden on such entities.

C. Congressional Review Act

95. The Commission will send a copy of this *Report and Order* to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

D. Implementation

96. In this *Report and Order*, we require that providers of non-line-powered, facilities-based, fixed, voice residential service, including fixed wireless service intended as POTS replacement, offer new subscribers at the point of sale, at the subscriber's option and expense, a backup power solution that provides 911 access for 8 hours during a commercial power loss. Except as noted below, this provision of our rules will become effective 120 days after publication of this *Report and Order* in the **Federal Register**. Within three years of the foregoing effective date of the 8-hour obligation, providers must also offer a 24-hour backup power solution. We seek to ensure that the measures we adopt are timely implemented so that consumers can begin to realize the benefits as soon as feasible, while allowing a reasonable time for providers to prepare. Except as noted below, the disclosure provisions of the rules will become effective 120 days after the Commission notifies the public that approval has been received from the Office of Management and Budget.

97. We delay the effective date of two of the rules we adopt herein for providers that have fewer than 100,000 domestic retail subscriber lines for an additional 180 days to afford ample time to modify their current practices as necessary to come into compliance with our rules. The obligation of these providers to offer 8 hours of backup power will become effective 300 days after publication of this *Report and Order* in the **Federal Register**. The disclosure obligations for these providers will become effective 300 days after the Commission notifies the public that approval has been received from the Office of Management and Budget. The obligation of such providers to offer 24 hours of backup

power will become effective on the same extended three-year schedule as for all other providers.

98. Such an accommodation addresses the concerns of some commenters that adopting mandatory backup power obligations for all customers will be particularly burdensome for providers with a small number of lines, and is in line with Commission precedent. While we do not think that the more limited backup power obligations that we adopt herein will be overly burdensome for any provider, we agree with ACA's suggestion that providers with a small number of lines are more resource-constrained and would benefit from additional time to obtain any necessary equipment and prepare materials and processes for disclosure, and prepare materials and processes for disclosure. We note that ACA asserts that smaller operators should be defined as those with fewer than 100,000 voice service customers, and cites the *Rural Call Completion Report and Order* in support of its position. However, we observe that the *Rural Call Completion Report and Order* did not define smaller providers in terms of the number of customers, but subscriber lines. We find that providing an accommodation to providers on the basis of subscriber lines, rather than subscribers, is reasonably designed to minimize burdens on smaller providers without compromising the effectiveness of the rules. The number of lines better reflects a provider's size and share of traffic than does the number of subscribers. We find that limited, additional time to comply with these aspects of our rules strikes the right balance between the particular circumstances and resource constraints of providers that serve fewer customers and ensuring that consumers have backup power options available in a timely manner.

99. For this purpose, we rely on the standard adopted in the 2013 *Rural Call Completion proceeding*. In the *Rural Call Completion Report and Order*, the Commission applied the requirements to providers of long-distance voice service who make the initial long-distance call path choice for more than 100,000 domestic retail subscriber lines. Accordingly, in this proceeding, in an effort to ensure a reasonable burden of compliance, we give providers with fewer than 100,000 domestic retail subscriber lines an additional 180 days to comply with the obligations adopted in this *Report and Order*.

V. Ordering Clauses

100. Accordingly, *it is ordered*, pursuant to sections 1, 4(i), and

251(e)(3) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 251(e)(3); section 101 of the NET 911 Improvement Act of 2008, Public Law 110–283, 47 U.S.C. 615a–1; and section 106 of the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 47 U.S.C. 615c, that this *Report and Order* in PS Docket No. 14–174 is adopted.

101. *It is further ordered* that part 12 of the Commission's Rules, 47 CFR part 12, is *hereby amended* as set forth in Appendix C of the full *Report and Order*.

102. *It is further ordered* that the requirements of this *Report and Order* will become effective as specified in paragraphs 96–99 herein.

103. *It is further ordered* that, pursuant to Section 801(a)(1)(A) of the Congressional Review Act, the Commission shall send a copy of this *Report and Order* to Congress and to the Government Accountability Office.

104. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Report and Order*, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects 47 CFR Part 12

Communications equipment, Security measures.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons set forth in the preamble, the Federal Communications Commission amends 47 CFR part 12 as follows:

PART 12—RESILIENCY, REDUNDANCY AND RELIABILITY OF COMMUNICATIONS

■ 1. The authority citation for part 12 is revised to read as follows:

Authority: 47 U.S.C. 151, 154(i), 154(j), 154(o), 155(c), 218, 219, 251(e)(3), 301, 303(g), 303(j), 303(r), 332, 403, 621(b)(3), 621(d); 47 U.S.C. 615a–1; and 47 U.S.C. 615c, unless otherwise noted.

■ 2. Section 12.5 is added to read as follows:

§ 12.5 Backup power obligations.

(a) *Covered service.* For purposes of this section, a Covered Service is any facilities-based, fixed voice service offered as residential service, including fixed applications of wireless service

offered as a residential service, that is not line powered.

(b) *Obligations of providers of a Covered Service to offer backup power.* Providers of a Covered Service shall, at the point of sale for a Covered Service, offer subscribers the option to purchase backup power for the Covered Service as follows:

(1) *Eight hours.* Providers shall offer for sale at least one option with a minimum of eight hours of standby backup power.

(2) *Twenty-four hours.* By February 13, 2019, providers of a Covered Service shall offer for sale also at least one option that provides a minimum of twenty-four hours of standby backup power.

(3) At the provider's discretion, the options in paragraphs (b)(1) and (2) of this section may be either:

(i) A complete solution including battery or other power source; or

(ii) Installation by the provider of a component that accepts or enables the use of a battery or other backup power source that the subscriber obtains separately. If the provider does not offer a complete solution, the provider shall install a compatible battery or other power source if the subscriber makes it available at the time of installation and so requests. After service has been initiated, the provider may, but is not required to, offer to sell any such options directly to subscribers.

(c) *Backup power required.* The backup power offered for purchase under paragraph (b) of this section must include power for all provider-furnished equipment and devices installed and operated on the customer premises that must remain powered in order for the service to provide 911 access.

(d) *Subscriber disclosure.* (1) The provider of a Covered Service shall disclose to each new subscriber at the point of sale and to all subscribers to a Covered Service annually thereafter:

(i) Capability of the service to accept backup power, and if so, the availability of at least one backup power solution available directly from the provider, or after the initiation of service, available from either the provider or a third party. After the obligation to offer for purchase a solution for twenty-four hours of standby backup power becomes effective, providers must disclose this information also for the twenty-four-hour solution;

(ii) Service limitations with and without backup power;

(iii) Purchase and replacement information, including cost;

(iv) Expected backup power duration;

(v) Proper usage and storage conditions, including the impact on

duration of failing to adhere to proper usage and storage;

(vi) Subscriber backup power self-testing and -monitoring instructions; and

(vii) Backup power warranty details, if any.

(2) *Disclosure reasonably calculated to reach each subscriber.* A provider of a Covered Service shall make disclosures required by this rule in a manner reasonably calculated to reach individual subscribers, with due consideration for subscriber preferences. Information posted on a provider's public Web site and/or within a subscriber portal accessed by logging through the provider's Web site are not sufficient to comply with these requirements.

(3) The disclosures required under this paragraph are in addition to, but may be combined with, any disclosures required under § 9.5(e) of this chapter.

(e) *Obligation with respect to existing subscribers.* Providers are not obligated to offer for sale backup power options to or retrofit equipment for those who are subscribers as of the effective date listed in paragraph (f) of this section for the obligations in paragraph (b)(1) of this section, but shall provide such subscribers with the annual disclosures required by paragraph (d) of this section.

(f) *Effective dates of obligations.* (1) Except as noted in paragraphs (b)(2) and (f)(2) of this section, the obligations under paragraph (b) of this section are effective February 16, 2016, and the obligations under paragraph (d) of this section are effective 120 days after the Commission announces approval from the Office of Management and Budget.

(2) For a provider of a Covered Service that (together with any entities under common control with such provider) has fewer than 100,000 domestic retail subscriber lines, the obligations in paragraph (b)(1) of this section are effective August 11, 2016, the obligations in paragraph (b)(2) of this section are effective as prescribed therein, and the obligations under paragraph (d) of this section are effective 300 days after the Commission announces approval from the Office of Management and Budget.

(g) *Sunset date.* The requirements of this section shall no longer be in effect as of September 1, 2025.

[FR Doc. 2015–24845 Filed 10–15–15; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF TRANSPORTATION**National Highway Traffic Safety Administration****49 CFR Part 571**

[Docket No. NHTSA–2015–0099]

Federal Motor Vehicle Safety Standard; Automatic Emergency Braking**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).**ACTION:** Grant of petition for rulemaking.

SUMMARY: This document grants the petition for rulemaking submitted by the Truck Safety Coalition, the Center for Auto Safety, Advocates for Highway and Auto Safety, and Road Safe America on February 19, 2015, to establish a safety standard to require automatic forward collision avoidance and mitigation systems on certain heavy vehicles. For several years, NHTSA has researched forward collision avoidance and mitigation technology on heavy vehicles, including forward collision warning and automatic emergency braking systems. The agency will continue to conduct research and to evaluate real-world performance of these systems through track testing and field operational testing. NHTSA will determine whether to issue a rule in the course of the rulemaking proceeding, in accordance with statutory criteria.

DATES: October 16, 2015.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may call Dr. Abigail Morgan in the Office of Crash Avoidance Standards at (202) 366–1810. For legal issues, you may call Mr. David Jasinski or Ms. Analiese Marchesseault in the Office of Chief Counsel at (202) 366–2992. You may send mail to these officials at: National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: On February 19, 2015, the Truck Safety Coalition, the Center for Auto Safety, Advocates for Highway and Auto Safety, and Road Safe America (hereon referred to collectively as the “petitioners”) submitted a petition to NHTSA. Their petition requested that the agency initiate rulemaking to establish a new Federal motor vehicle safety standard to require vehicle manufacturers to install forward collision avoidance and mitigation (FCAM) systems on all vehicles with a gross vehicle weight rating (GVWR) of 10,000 pounds or more. The petitioners claimed that FCAM systems have the potential to provide significant safety, economic, and societal benefits.

On May 4, 2015, the Commercial Vehicle Safety Alliance (CVSA) submitted a letter supporting the petition for rulemaking. However, CVSA recommended that the mandate for FCAM systems apply to vehicles with a GVWR of 10,001 pounds or more (rather than 10,000 pounds or more) to better conform to existing commercial motor vehicle safety classes.

There are a number of terms being used by industry and regulators for FCAM technology, including forward collision warning (FCW), crash imminent braking (CIB), dynamic brake support (DBS), automatic emergency braking (AEB), and collision mitigation braking (CMB). Consistent with the terminology used in the petitioners’ request, in this notice, the FCAM technologies of focus are the systems that combine FCW alert signals with CMB automatic braking capability.

FCAM systems use forward-looking sensors, typically radars and/or cameras, to detect vehicles in the roadway. When a rear-end crash is imminent, the FCW system warns the driver of the threat. If the driver takes no action, such as braking or steering, or if the driver does brake but not enough to avoid the crash, a CMB or AEB system may automatically apply or supplement the brakes to avoid or mitigate the rear-end crash.

In their petition for rulemaking, the petitioners cited estimated safety benefits from a 2012 research study¹ conducted by the University of Michigan Transportation Research Institute (UMTRI), which evaluated the performance and effectiveness of these current and future generation systems. They also identified the systems that are commercially available. The petitioners believe that mandating technology through regulation is the fastest way to ensure the potential safety benefits. Additionally, they believe that additional safety benefits may be achieved from future FCAM systems that may have higher levels of performance than the current systems and that may be able to respond to additional crash scenarios other than rear-end crashes, such as vehicle-to-pedestrian crashes. Furthermore, the petitioners believe that a mandate would cause the system costs to decrease due to high production volumes.

For several years, NHTSA has been conducting research on heavy vehicle

FCAM technologies. This research includes test track evaluations of first generation systems, evaluation of driver-warning interface effectiveness, and an ongoing field operational test of production systems. Based on this research, the agency agrees with the petitioners that FCAM systems have the potential to save lives by preventing or reducing the severity of rear-end crashes.

The industry has indicated that next generation automatic emergency braking systems for truck tractors will be commercially available later this year and will have improved performance that enables the vehicle to warn the driver and automatically brake in response to stationary lead vehicles. In addition to the increased performance from the next generation systems, industry is also expected to begin production of automatic emergency braking systems on air-braked single unit trucks with a GVWR of more than 26,000 pounds in the near future.

The agency’s test experience has been limited to first generation production systems on truck tractors and a prototype system on a motorcoach, and the agency is aware of a few vehicles with a GVWR greater than 10,000 pounds and less than or equal to 26,000 pounds sold in the U.S. currently equipped with AEB systems. The agency plans to test the next generation systems as they become available, including AEB systems that are installed on vehicles with a GVWR greater than 10,000 pounds and less than or equal to 26,000 pounds. If available, NHTSA would consider this additional information in the rulemaking.

The European Union (EU) Commission Regulation No. 347/2012 requires an advanced emergency braking system (AEBS) with forward collision warning on most new heavy vehicles, with some exceptions.² The test scenarios, vehicle speeds, and performance criteria in EU Commission Regulation No. 347/2012 differ from the test criteria that NHTSA developed for its light vehicle automatic emergency braking evaluation that the agency plans to add to its New Car Assessment Program (NCAP), which has been the basis for the test criteria used to evaluate heavy vehicles. The agency will consider the test criteria required by the European regulation, as it

¹ Woodrooffe, J., et al., Performance Characterization and Safety Effectiveness Estimates of Forward Collision Avoidance and Mitigation Systems for Medium/Heavy Commercial Vehicles, Report No. UMTRI–2011–36, UMTRI (August 2012). Docket No. NHTSA–2013–0067–0001.

² Commission Regulation (EU) No 347/2012; of 16 April 2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council with respect to type-approval requirements for certain categories of motor vehicles with regard to advanced emergency braking systems. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:109:0001:0017:EN:PDF>.

continues to develop its heavy vehicle test procedures and performance metrics.

Considering the information before the agency, including the information referenced in the petition, NHTSA grants the February 19, 2015 petition in accordance with 49 CFR part 552 and initiates a rulemaking proceeding with respect to forward collision avoidance and mitigation systems on vehicles with a GVWR greater than 10,000 pounds. The granting of the petition from Truck Safety Coalition, the Center for Auto Safety, Advocates for Highway and Auto Safety, and Road Safe America does not mean that the agency will issue a final rule. The determination of whether to issue a rule is made after study of the requested action and the various alternatives in the course of the rulemaking proceeding, in accordance with statutory criteria.

Authority: 49 U.S.C. 322, 30111, 30115, 30117, 30162, 30166, and 49 CFR part 552; delegation of authority at 49 CFR 1.95.

Raymond R. Posten

Associate Administrator for Rulemaking.

[FR Doc. 2015-26294 Filed 10-15-15; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 300, 600, 660, and 665

[Docket No. 070516126-5907-04]

RIN 0648-AV12

International Affairs; High Seas Fishing Compliance Act; Permitting and Monitoring of U.S. High Seas Fishing Vessels

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

ACTION: Final rule.

SUMMARY: This final action sets forth regulatory changes to improve the administration of the High Seas Fishing Compliance Act program and the monitoring of U.S. fishing vessels operating on the high seas. This final rule includes, for all U.S. fishing vessels operating on the high seas, adjustments to permitting and reporting procedures. It also includes requirements for the installation and operation of enhanced mobile transceiver units (EMTUs) for vessel monitoring, carrying observers on vessels, reporting of transshipments taking place on the high seas, and

protection of vulnerable marine ecosystems. This final rule has been prepared to minimize duplication and to be consistent with other established requirements.

DATES: This rule is effective January 14, 2016.

FOR FURTHER INFORMATION CONTACT:

Mark Wildman, Trade and Marine Stewardship Division, Office for International Affairs and Seafood Inspection, NMFS (phone 301-427-8386 or email *mark.wildman@noaa.gov*).

SUPPLEMENTARY INFORMATION:

Background

The purposes of the High Seas Fishing Compliance Act (HSFCA; 16 U.S.C. 5501 *et seq.*) are (1) to implement the Food and Agriculture Organization of the United Nations (FAO) Agreement to Promote Compliance with International Conservation and Management Measures by Fishing Vessels on the High Seas (Compliance Agreement) and (2) to establish a system of permitting, reporting and regulation for vessels of the United States fishing on the high seas. 16 U.S.C. 5501. "High seas" is defined in the HSFCA and its implementing regulations as waters beyond the territorial sea or exclusive economic zone (or the equivalent) of any nation, to the extent that such territorial sea or exclusive economic zone (or the equivalent) is recognized by the United States. 16 U.S.C. 5502 (3); 50 CFR 300.11.

The HSFCA authorizes a system of permitting U.S. fishing vessels that operate on the high seas to satisfy the obligation of Parties to the Compliance Agreement (Parties) to require that fishing vessels flying their flags obtain specific authorization to operate on the high seas. The HSFCA requires the Secretary of Commerce (Secretary) to establish conditions and restrictions on each permit issued under HSFCA as necessary and appropriate to carry out the obligations of the United States under the Compliance Agreement. 16 U.S.C. 5503 (d). At a minimum, such conditions and restrictions must include the marking of the permitted vessel in accordance with the FAO Standard Specifications for the Marking and Identification of Fishing Vessels, and reporting of fishing activities. Parties are also responsible for ensuring that their authorized vessels do not undermine conservation and management measures, including those adopted by international fisheries management organizations, or by treaties or other international agreements. Accordingly, the HSFCA prohibits the use of fishing

vessels on the high seas in contravention of international conservation and management measures recognized by the United States. 16 U.S.C. 5505(1). A list of the international conservation and management measures recognized by the United States is published by NMFS in the **Federal Register** from time to time, in consultation with the Secretary of State, as required by section 5504(e) of the HSFCA. The last such notice was published on May 19, 2011 (76 FR 28954). NMFS reinforces this prohibition by requiring a high seas fishing permit for any vessel operating on the high seas and, through the permit, authorizing only those activities that would not undermine international conservation and management measures recognized by the United States. The HSFCA also gives NMFS discretion to impose permit conditions and restrictions pursuant to other applicable law, such as the Endangered Species Act (ESA) and the Marine Mammal Protection Act, in addition to international conservation and management measures recognized by the United States. *See* 16 U.S.C. 5503(d); *Turtle Island Restoration Network v. National Marine Fisheries Service*, 340 F.3d 969 (9th Cir. 2003).

Finally, the HSFCA authorizes NMFS to promulgate regulations "as may be necessary to carry out the purposes of the Agreement and [the Act]," including its permitting authorities. 16 U.S.C. 5504(d). In promulgating such regulations, NMFS shall ensure that "[t]o the extent practicable, such regulations shall also be consistent with regulations implementing fishery management plans under the Magnuson-Stevens Fishery Conservation and Management Act," 16 U.S.C. 1801 *et seq.*, which provides broad authority to establish measures for the conservation and management of fisheries. *Id.* at 1853(b)(14).

Regulations implementing the HSFCA were first promulgated in 1996 (61 FR 11751, March 22, 1996). The initial regulations included application and issuance procedures for high seas fishing permits. Subsequent regulations promulgated in 1999 (64 FR 13, January 4, 1999) specified how high seas fishing vessels must be marked for identification purposes and required vessel owners and operators to report catch and fishing effort when fishing on the high seas.

On April 13, 2015, NMFS published a notice of proposed rulemaking for this action (80 FR 19611) to codify NMFS' procedures for reviewing its high seas fishing authorizations under environmental laws, particularly the

ESA and National Environmental Policy Act (NEPA). Another objective of this action is to improve the monitoring of U.S. fishing vessels operating on the high seas. In order to enhance the U.S. government's ability to ensure compliance with international conservation and management measures. Furthermore, this action describes how NMFS will, through high seas permit conditions and restrictions, address impacts to vulnerable marine ecosystems (VMEs) from bottom fishing consistent with international conservation and management measures recognized by the United States and United Nations General Assembly resolutions regarding VMEs. Additionally, NMFS will continue to assess the impact of the long-term exemption on the use of an EMTU, set forth in § 300.337(d)(2) of this rule, on the efficacy of the HSFCA VMS provisions and may make appropriate adjustments, including elimination of the long-term exemption, through a future rulemaking.

Responses to public comments received on the proposed rule are set forth below.

Changes From the Proposed Rule

NMFS has made one change to the final rule in light of comments received on the proposed rule. Section 300.333(i) in the proposed rule, which addressed provisions for permit modification and revocation, has been modified to clarify that modification, suspension, or revocation of a high seas permit will be carried out consistent with the Administrative Procedure Act and other applicable law. Additional detail is provided in Responses to Public Comments section below.

Responses to Public Comments

NMFS received 18 public comments on the proposed rule. Comments were received from the Western Fish Boat Owners Association, the American Albacore Fishing Association, the Hawaii Longline Association, and individual west coast albacore fishers potentially affected by new requirements in this rule.

General Comments

NMFS received numerous comments from west coast albacore fishers who voiced their view that the proposed rule, if finalized, would impose considerable and unnecessary burdens. These fishers noted that the additional burden on the fleet resulting from the requirements contained in this rule would have adverse impacts on vessels, families, onshore support businesses, local communities, and consumers.

Commenters noted the rule could reduce access to high seas fisheries by U.S. vessels and ensure that an increasing portion of catch would be taken by foreign vessels that are not subject to similar requirements. Commenters also noted that the U.S. albacore fishery already has mandatory logbook requirements that would not change under this new rule, and the information in these logbooks provides all the information necessary to monitor this fishery.

Response: NMFS recognizes the new EMTU and observer requirements will primarily impact those fishers who do not currently have to comply with such requirements in domestic fisheries or in international fisheries managed pursuant to conservation and management measures adopted by Regional Fishery Management Organizations (RFMOs). NMFS has therefore made efforts to mitigate these new burdens by informing fishers of possible reimbursement for the cost of purchasing an EMTU unit (see http://www.nmfs.noaa.gov/ole/slider_stories/2015/3june15_vms_program_codifies_requirements.html). Additionally, NMFS notes that observer coverage will not be required under this rule where such coverage is already mandated under other legal authorities. NMFS will also carefully take into consideration both the scientific need for observer coverage as well as the characteristics of the fishery when designating high seas vessels for observer coverage.

These new requirements are deemed necessary to improve U.S. capacity to monitor its vessels' compliance with domestic laws, including those used to implement RFMO requirements (both for those RFMOs to which we are a party as well as those recognized by the United States for purposes of the Compliance Act). This will enhance the United States' ability to comply with its international obligations, including the obligation to report high seas fishery data to the U.N. Food and Agriculture Organization. NMFS believes the cost of complying with these new requirements is justified in light of the benefits that will be gained from a uniform level of real-time monitoring of all high seas activities conducted by U.S. fishers.

Requirements for Enhanced Mobile Transmitting Units (EMTUs)

Comment 1: Several west coast albacore fishers noted that under WCPFC regulations, EMTUs are required for all vessels that fish west of the 150W line. This includes some of the larger U.S. albacore vessels. These fishers commented that EMTUs should not be required for pole and line and

troll vessels fishing for albacore east of the 150W line. These fishers also noted that the Inter-American Tropical Tuna Commission (IATTC) only requires VMS on vessels greater than 24 meters in length and the regulations developed by the Pacific Fishery Management Council for the albacore fishery under its purview do not require VMS. It was also noted that Canadian vessels under 24 meters are not required to have VMS.

Response: In light of U.S. obligations under the Compliance Agreement to ensure that U.S. fishing vessels on the high seas do not engage in any activity that undermines the effectiveness of international conservation and management measures, NMFS considers it necessary to require all vessels permitted to fish on the high seas be equipped with EMTUs. NMFS also notes that under its existing regulations, all U.S. vessels with WCPFC endorsement permits must continuously operate a VMS unit while at sea, regardless of where the vessel operates, *i.e.*, east or west of the 150W meridian.

Comment 2: Several west coast albacore fishers noted that the mandatory EMTU requirement is onerous, particularly since most albacore vessels fish inside the U.S. EEZ and only occasionally go out into high seas waters. With the new EMTU requirement, however, these commenters noted that many vessels would forgo obtaining the high seas permit because of the cost associated with procuring and operating an EMTU.

Response: NMFS notes that, in contrast with logbooks, VMS/EMTU reports are received in real time, enabling more timely monitoring and enforcement. NMFS recognizes the additional cost burden associated with procuring and operating EMTUs and offers a reimbursement program to provide eligible vessel owners with up to \$3,100 towards the cost of procuring an EMTU unit (see "further information" below).

Comment 3: Since the focus of the proposed rule is on the activities of U.S. fishers on the high seas, several west coast albacore fishers questioned the necessity of a requirement for the EMTU to transmit while a U.S. vessel is still within the U.S. EEZ.

Response: NMFS considered the alternative of only requiring EMTU operation on the high seas but allowing units to be powered down while a vessel is in the U.S. EEZ or in the EEZ of another country, but determined that such actions would weaken the effectiveness of using EMTU position information to monitor the locations of high seas fishing vessels. Allowing power-downs whenever in the U.S. EEZ,

in addition to the in-port and long-term exemptions provided in the rule, could also encourage non-compliance and undermine NMFS' ability to monitor U.S. high seas fishing vessels.

Comment 4: West coast albacore fishers noted that requirements in the rule to notify NOAA's Office of Law Enforcement (OLE) of EMTU power-up during office hours is burdensome and waiting for email confirmation from OLE regarding the receipt of such notifications would be another burdensome delay.

Response: NMFS recognizes that OLE office hours are somewhat constraining, but notes that vessel owners could choose to leave EMTUs on and not power them down to help alleviate pre-planning for turning on such units. NMFS also notes such power up notifications from fishers to OLE may take place after office hours although OLE acknowledgement of receipt will take place during business hours. OLE makes best efforts to minimize delays in its responses to fishers.

Comment 5: Several west coast fishers stated their view that the initial cost and expenses associated with EMTU installation and operation are significant. They furthermore noted that the lost income resulting from downtime while having an EMTU unit installed and the additional expense of travelling to a different location to have an EMTU unit installed are not included in NMFS cost estimates.

Response: NMFS recognizes the additional cost burden associated with procuring EMTUs and did account for the time necessary to have an EMTU installed as part of its cost estimate. NMFS also has a reimbursement program that will offer up to \$3,100 towards the cost of the EMTU unit for eligible vessel owners (see "further information" below). Such units can usually be installed without unduly impacting the vessel's normal operations.

Comment 6: Several west coast albacore fishers noted that, with regard to the proposed requirement for high seas vessels to possess a backup communications device in the event of an EMTU failure, it was unclear what kind of backup communications device would be required. These fishers noted that although U.S. vessels are required by the Coast Guard to carry a single side band radio when offshore, such a radio may not be capable of meeting the functionality requirements delineated by NMFS in the proposed rule.

Response: NMFS notes that as long as the communications device is two-way and capable of real-time communications per § 300.337(k) in the

final rule, NMFS would allow fishers to use a device of their choosing whether it be a satellite phone or some other communications device, including a single side band radio.

Comment 7: West coast albacore fishers expressed their view that there are no bycatch issues in this fishery, and there are no closed areas where pole and line and troll vessels fish. Because this is the case, these fishers view the EMTU requirement as being unnecessary and creating a considerable financial and administrative burden.

Response: Although there may be little bycatch of protected species in the west coast albacore fishery, NMFS is required under the Compliance Agreement to monitor all its high seas fishing vessels and believes the enhanced compliance monitoring and enforcement benefits obtained from the EMTU requirement justify the cost of procuring and operating such equipment, a significant portion of which may be lessened through the reimbursement program for eligible fishers needing to procure an EMTU. Furthermore, VMS monitoring allows the U.S. government to comply with its international obligations by ensuring that vessels not authorized to fish in certain areas (for example, west of 150 degrees longitude without a WCPFC Area Endorsement) are not fishing there.

Requirements for Observers

Comment 1: Several west coast albacore fishers noted that the new observer requirement would be problematic due to the small size of most U.S. pole and line and troll vessels fishing for albacore off the west coast. It was furthermore noted that the IATTC does not have observer requirements and neither do regulations developed by the Pacific Fishery Management Council for the albacore fishery under its purview.

Response: NMFS notes that the new observer requirement is consistent with regulations for Pacific HMS fisheries (including the north Pacific albacore fishery) at 50 CFR 660.719(a), which states that "all fishing vessels with permits issued under this subpart and operating in HMS fisheries, including catcher/processors, at-sea processors, and vessels that embark from a port in Washington, Oregon, or California and land catch in another area, may be required to accommodate an NMFS certified observer on board to collect scientific data." That being said, NMFS would carefully take into consideration both the scientific need for observer coverage as well as the characteristics of the fishery when designating high seas vessels for observer coverage.

Comment 2: The Hawaii Longline Association (HLA) noted that the proposed rule includes a new requirement stating that "[w]here observer coverage is not otherwise required by other regulations or relevant RFMO conservation and management measures, NMFS may select for at-sea observer coverage any vessel that has been issued a high seas fishing permit." Although the preamble to the proposed rule clarifies that this requirement "would not be invoked by NMFS if the vessel will already be carrying an observer pursuant to other legal authorities," HLA believes it does not speak to the situation where a fishery is already generally subject to a rigorous observer monitoring program.

Response: NMFS will take other applicable observer coverage requirements into consideration in our assignment of observers under this final rule. As stated in the preamble of the proposed rule, this requirement would not be invoked by NMFS if the vessel will already be carrying an observer pursuant to other legal authorities. NMFS does not view amending the regulatory text as desirable since it could lessen the agency's flexibility in deploying scientific observers to monitor unforeseen issues that could arise unexpectedly in a high seas fishery.

Provisions for Permit Modification and Revocation

Comment 1: HLA notes that the proposed rule includes a new provision that would allow NMFS to "modify, suspend, or revoke high seas permits if permitted activities impact living marine resources in ways that were not foreseen or anticipated at the time of permit issuance or are in contravention of an international conservation and management measure or are in violation of any provision of domestic law." HLA is concerned with the ambiguity of the phrase "impact living marine resources in ways that were not foreseen or anticipated" and recommends NMFS modify the proposed § 300.333(i) to eliminate the phrase "may impact living marine resources in ways that were not foreseen or anticipated at the time of permit issuance" and provide a more transparent standard for the regulated community. In addition to this proposed revision, HLA believes NMFS should provide an administrative process whereby the permit holder may contest the permit modification, suspension, or revocation. HLA notes its proposed revisions would require NMFS to provide reasonable notice to the permit holder before a permit is modified or revoked, as well as an opportunity to be

heard, consistent with due process requirements.

Response: Under this rule, consistent with international conservation and management measures and applicable law, NMFS authorizes the issuance of high seas fishing permits for high seas fisheries where fishing activities have been analyzed in accordance with the ESA, NEPA, and other applicable law. However, new information about fishing activities and impacts to living marine resources may arise after a fishery is authorized and permits are issued. Recognizing this, § 300.333(i) provides NMFS with authority to modify, suspend, or revoke a permit, as needed. Prior to doing so, NMFS would provide affected permit holders the new information that was not available and therefore not considered at the time of permit issuance, along with the rationale for the proposed permit modification, suspension, or revocation. In response to comments, NMFS has revised the final rule to refer to impacts that were “not considered” (as opposed to “not foreseen or anticipated”) at the time of permit issuance to provide more clarity. Broad language is necessary here because it is impossible to anticipate and codify all of the types of new information that could lead NMFS to modify, suspend, or revoke an HSFCA permit. However, the final rule also explains that, in the event of a potential permit change, NMFS would notify affected permit holders and provide an opportunity to respond, consistent with the Administrative Procedure Act (APA) and other applicable law. Individual permit infractions will continue to be handled in accordance with procedures at 15 CFR part 904. Beyond the permit change provision of § 300.333(i), NMFS notes that § 300.334(d)–(f) provides broader authority to delete a fishery from the authorized fisheries list through rulemaking. Among other things, a relevant consideration is whether fishing activities would detrimentally affect the well-being of a regulated species of fish, marine mammal, or ESA-protected species. If NMFS were to delete an authorized fishery, any activities on the high seas related to that fishery would be prohibited.

Procedures for Deletion of a Fishery From the List of Authorized High Seas Fisheries

Comment 1: The HLA stated it is essential that the process to delete a fishery from the list of authorized high seas fisheries involve a full administrative process, including issuance of a proposed rule and the opportunity for public comment, similar

to the Marine Mammal Protection Act (MMPA) List of Fisheries. The HLA view is that the proposed regulations only provide such process for the addition of fisheries—not for the deletion of fisheries. In HLA’s view, such a deletion of a fishery without notice and the opportunity for comment would violate due process requirements.

Response: Section 300.334(d) of the rule provides for rulemaking procedures to take place in the case of any revision (addition or deletion) to the list of authorized high seas fisheries and § 300.334(f) reiterates that NMFS will issue a final rule announcing any deletion from the list of authorized high seas fisheries. NMFS would conduct the rulemaking consistent with the APA which generally requires publication of a proposed and final rule, opportunity for public comment and delayed effectiveness for a final rule, but also provides for good cause waiver of notice and comment when impracticable, unnecessary, or contrary to the public interest. Any such action would also be conducted consistent with the ESA, MMPA, MSA, and other applicable law.

Conditions for Obtaining or Renewing a Permit or Authorization

Comment 1: The HLA notes that § 300.334(b)(2) of the proposed regulations, if finalized, will require a new applicant for a high seas permit to “obtain and renew any appropriate permits or authorizations.” Based on HLA’s past experience, there are situations that may arise in which a required authorization by NMFS for a given fishery is overdue (such as the issuance of a negligible impact determination under the MMPA) as a result of agency delay. In this situation, vessels in the fishery that already have permits are typically allowed to continue fishing under a temporary extension, which is issued by an agency letter. It is not clear to HLA whether § 300.334(b)(2) will prevent a new vessel from receiving a high seas permit or authorization in this situation. HLA recommends that NMFS clarify in the preamble to the final rule or in the final regulations that this condition will not apply to situations in which an authorization cannot be obtained as a result of agency delay or fault by the agency.

Response: NMFS recognizes there are temporary situations such as those noted by HLA. We believe that the phrase “permit or authorization” in § 300.334(b)(2) of the final rule is broad enough to encompass a temporary extension of a permit issued via an agency letter.

Further Information for High Seas Vessel Owners Applying for Reimbursement for Purchase of a Type-Approved VMS/EMTU Unit

High seas vessel owners that do not currently possess VMS/EMTU units type-approved for use on the high seas may apply for reimbursement by contacting the VMS reimbursement program at the Pacific States Marine Fisheries Commission (www.psmfc.org).

Vessel owners are reimbursed on a first-come, first-served basis until funds for the reimbursement program are exhausted. The standard processing time is within 30 days of a completed application. Since funding for these reimbursements is only available until the end of 2015, NOAA recommends VMS installations/activations be made no later than November 15, 2015, and all applications for reimbursement be submitted to the Pacific States Marine Fisheries Commission no later than 5 p.m./PST on November 30, 2015.

Classification

This final rule is published under the authority of the High Seas Fishing Compliance Act (16 U.S.C. 5501 *et seq.*). The NMFS Assistant Administrator has determined that this final rule is consistent with this and other applicable laws.

The Office of Management and Budget has determined that this rule is not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

A Final Regulatory Flexibility Analysis (FRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The FRFA describes the economic impact this final rule will have on small entities. This FRFA incorporates the Initial Regulatory Flexibility Analysis (IRFA) published in the **Federal Register** on April 13, 2015 (80 FR 19611). A description of the action, why it is being considered, and the legal basis for this action are contained above in the **SUPPLEMENTARY INFORMATION** section. The analysis follows. A copy of the full FRFA is available from NMFS (see **FOR FURTHER INFORMATION CONTACT**).

Description and Estimate of the Number of Small Entities

The final rule will apply to owners and operators of U.S. fishing vessels operating on the high seas, including harvesting vessels, refrigerated cargo vessels, and other vessels used to support fishing. There are approximately 600 U.S. vessels permitted under the HSFCA to fish on the high seas. The majority of these

permitted vessels are longliners, purse seiners, trollers, or pole and line vessels that fish for highly migratory species. There are also small numbers of gillnetting, squid jigging, hand or other lining, multipurpose, and trawl vessels.

In this RFA analysis, an individual vessel is the proxy for each business entity. Although a single business entity may own multiple vessels, NMFS does not have a reliable means at this time to track ownership of multiple vessels to a single business entity. Based on limited financial information about the affected fishing vessels, NMFS believes that all the affected fish harvesting businesses, except for the Pacific tuna purse seine vessels, are small entities as defined by the RFA; that is, they are independently owned and operated and not dominant in their fields of operation, and have annual receipts of no more than \$20.5 million.

Projecting Reporting, Record-Keeping, and Other Compliance Requirements

For each element of the final rule, the analysis of impacts to small entities is described below.

Permit Application Process. NMFS currently authorizes fisheries on the high seas only after appropriate reviews are completed pursuant to the ESA, MMPA, NEPA, and other applicable law. Applicants select from a list of such authorized fisheries when applying for a high seas fishing permit. The final rule will codify this procedure. Vessel owners and operators apply for a high seas fishing permit every 5 years, paying an application fee currently set at \$129 and completing the application form, which is estimated to take 30 minutes. The rule will not change these burdens.

The final rule is explicit about the requirement that vessels harvesting or participating in operations on the high seas in support of harvesting, such as transshipment and provision of supplies or fuel, have on board a valid high seas fishing permit. NMFS expects this aspect of the final rule to result in few additional applications for high seas permits, if any, because transshipment of fish on the high seas is prohibited in some fisheries and, where it is not prohibited, records show few instances of transshipment. NMFS is not aware of any U.S. vessels that provide supplies or fuel to harvesting vessels on the high seas.

The rule will require a photograph of the high seas fishing vessel to be submitted with the permit application. The time necessary to photograph the vessel, print or scan the photograph, and attach it to the application is

estimated to take 30 minutes per application.

The final rule will allow a person, which could include an organization or a group of persons, to request that NMFS add a fishery to the list of fisheries authorized on the high seas. A request will need to include the following information:

(a) The species (target and incidental) expected to be harvested and the anticipated amounts of harvest and bycatch.

(b) The approximate times and places fishing will take place, approximate number of vessels participating, and the type, size, and amount of gear to be used.

(c) A description of the specific area that may be affected by the fishing activities.

(d) A description of any anticipated impacts on the environment, including impacts on fish stocks, marine mammals, species listed as threatened or endangered under the ESA or their critical habitat.

(e) If requested by NMFS, any additional information necessary for NMFS to conduct analyses under ESA, MMPA and NEPA.

Making the request to add an authorized fishery is expected to take approximately 110 hours. This time would be spent gathering and compiling the required information. NMFS does not expect such requests on a regular basis. For the purposes of this FRFA, NMFS estimates that one request might be submitted every 5 years. The impact from this aspect of the final rule is not expected to be significant because this is not a requirement, but an option for the public, and such requests are expected to be made infrequently.

Installation and Operation of EMTUs. The final rule will require the installation of EMTUs on all high seas fishing vessels. The EMTU will need to be operated at all times, except when the vessel will be at a dock or permanent mooring for more than 72 consecutive hours, or when the vessel will not operate on the high seas or in any fishery that requires EMTU operation for more than 30 consecutive days. Notices prior to EMTU power-down and power-up will need to be provided to NMFS.

Under the final rule, approximately 200 of the currently permitted high seas fishing vessels will need to install an EMTU. The remaining 400 or so vessels currently holding high seas fishing permits are already subject to EMTU requirements and will not bear any additional compliance costs as a result of this final rule.

The majority of the approximately 200 affected vessels are albacore trollers or pole and line vessels operating in the Pacific Ocean. These vessels have generally not been subject to VMS requirements contained in other regulations. The cost of compliance with this requirement includes the cost of purchase, installation, maintenance, and operation of the EMTU. The costs of purchase and installation are treated as one-time costs because this analysis shows costs just in the near-term future. Table 1 summarizes the costs associated with the EMTU requirement. A description of the estimates and calculations used in Table 1 is provided below the table.

TABLE 1—ESTIMATED COSTS OF COMPLIANCE WITH EMTU REQUIREMENTS

Description	Cost
EMTU purchase	Up to \$3,100
Installation cost (one-time)	\$50–400 (\$400 used for estimation)
Daily position report costs (Hourly, 24/day; \$0.06/report *24 reports/day).	\$1.44
Annual position report cost per vessel (\$1.44/day * 365 days/year).	\$525/vessel
Annual EMTU maintenance cost.	\$50–100 (\$100 used for estimation)
Total cost per vessel (Year 1; unit + installation + position reports).	\$4025
Total cost per vessel after reimbursement of EMTU cost (for eligible vessels only).	\$925
Cost per vessel (Year 2 and beyond; position reports and EMTU maintenance).	\$625/vessel
Number of affected vessels ..	200
Total cost (Year 1; total cost per vessel before reimbursement * number of affected vessels).	\$805,000
Total cost (Year 2 and beyond; total cost per vessel * number of affected vessels).	\$125,000

Units must be installed by a qualified marine electrician. Based on experience in other fisheries with EMTU requirements, NMFS believes that installation cost can range from \$50 to \$400, depending on the vessel, proximity to the installer, and the difficulty of the installation. For estimation purposes, \$400 was used to calculate the costs of compliance with this final rule.

The cost of transmitting data through the EMTU depends on the type of

EMTU installed and the communication service provider selected. For the purposes of this rulemaking, NMFS is assuming the cost of EMTU position data transmissions is approximately \$0.06 per transmission. This equates to \$1.44 per day for the location reports, at a rate of one transmission per hour. Providing position reports throughout the year will cost a high seas fishing vessel \$525 (365 days per year * 24 position reports per day * \$0.06 = \$525).

The EMTU may be powered down if the vessel will be at the dock or mooring for more than 72 consecutive hours or if the vessel, for 30 or more consecutive days, will not be operating on the high seas or participating in a fishery that requires EMTU operation. A message notifying NMFS of the power-down must be sent to NMFS prior to powering down the unit and again when the EMTU will be powered back up. If an EMTU is powered down for portions of the year, the actual annual cost of transmitting position data will be less. Thus the annual costs of EMTU operation will vary among individual vessels depending on the number of days an EMTU may be powered down.

The cost of compliance for vessel owners is estimated to be \$4025 per vessel in the first year (Table 1). This is the cost of compliance prior to receiving reimbursement for the cost of the EMTU. Reimbursement funds of up to \$3,100 per VMS unit will reduce the cost to \$925 per vessel, on average, for reimbursement-eligible vessels. The cost of operating the EMTU in year two and beyond will include the cost of sending position reports and maintenance and is estimated to be \$625.

Aside from the costs of purchase, installation, and operation of EMTUs, vessel owners or operators will need to spend time purchasing a unit, having it installed, and submitting an installation and activation report form. These steps are estimated to take an average of 4 hours. The notices prior to power-down and powering back up the EMTU are estimated to take 10 minutes each.

The compliance cost of obtaining, carrying on board, and monitoring communication devices required to be used in the event of an EMTU failure is expected to be zero, as NMFS believes all affected small entities already carry and monitor such devices.

Requirement to Carry an Observer. Under the final rule, a high seas fishing vessel will be required to carry an observer for the duration of a fishing trip, if so selected by NMFS. When an observer is deployed pursuant to this rule, NMFS will pay the cost of the observer's salary and benefits. Most high seas fishing vessels are already subject

to requirements for carrying an observer. For example, in the shallow-set and deep-set longline sectors of the Hawaii longline fleet, 100 percent and approximately 20 percent of fishing trips, respectively, are covered by observers. In authorized fisheries where observers are placed on all participating vessels pursuant to other regulations, the compliance cost of the final rule will be nil.

In high seas fisheries where only a portion of the high seas fishing vessels are selected for observer coverage, the possibility of being selected to carry an observer may increase under this final rule. However, as noted in response to Comment 8 above, NMFS would carefully take into consideration both the scientific need for observer coverage as well as the characteristics of the fishery when designating high seas vessels for observer coverage. Vessels that are not already subject to any other observer requirements may be selected to carry observers. This includes, but is not limited to, South Pacific albacore trollers, purse seine vessels of Class 5 or smaller participating in the Eastern Pacific tuna fisheries, and some longline vessels in Western Pacific pelagic fisheries.

When a vessel is selected for observer coverage under this rule, the vessel owner or operator will be required to provide NMFS a notice of their next fishing trip. This notification is estimated to take 5 minutes and cost \$1 in communication costs.

For trips on which an observer is deployed under this new requirement, the affected entity will at least be responsible for the costs associated with providing the observer with food, accommodations, and medical facilities. These costs are expected to be \$20 to \$50 per day. Assuming a high seas fishing trip averages 20 days in duration, the estimated cost of compliance for accommodating an observer on a vessel would be between \$400 and \$1,000.

Transshipment Notices and Reports.

For owners and operators of vessels involved in offloading or receiving a transshipment of fish or fish product on the high seas, the final rule will require vessel owners or operators to provide to NMFS notice of transshipments at least 36 hours prior to any transshipment on the high seas and to submit reports of transshipment following the transshipment events.

Transshipment is also regulated under other applicable law. For example, in the Atlantic Ocean, transshipments (the offloading, unloading, or transferring of fish or fish products from one vessel to another) are generally prohibited, with

some exceptions. In the Pacific Ocean, purse seine vessels are prohibited from transshipping in some instances. NMFS is aware that during 2006 to 2009, four to eight vessels offloaded longline-caught fish each year and four to eight vessels received longline-caught fish each year. It is likely that most of these transshipments took place at sea by the Hawaii-based longline fleet, but it is unknown how many of these transshipments took place on the high seas. NMFS also has data on past transshipments on the high seas involving a few U.S. albacore troll vessels.

Each transshipment notice is estimated to take about 15 minutes and no more than \$1 in communication costs to prepare and submit to NMFS.

Each transshipment report is estimated to take about 60 minutes and \$1 in communication costs to prepare and submit to NMFS. Thus, for each transshipment event on the high seas, the time burden is estimated to be 1 hour and 15 minutes and cost \$2 for each U.S. flagged vessel involved in the transshipment.

Reporting Requirements. Existing regulations require submission of high seas fishing logbooks. This final rule deletes that requirement under the HSFCA regulations, and instead, provides that owners and operators of high seas fishing vessels use the reporting forms developed for their authorized fisheries to report high seas catch and fishing effort information. Given that the former reporting requirements would not be changed in a substantive way, the associated compliance cost is unchanged.

Summary. The final rule may increase the cost of operating on the high seas for all affected entities. Fulfillment of these requirements is not expected to require any professional skills that the vessel owners and operators do not already possess.

Significant Alternatives Considered

NMFS attempted to identify alternatives that would accomplish the objectives of the rulemaking and minimize any significant economic impact of the final rule on small entities.

The alternative of taking no action was rejected because it would fail to achieve the objectives of the rulemaking.

NMFS evaluated an option to rely on existing permit programs, other than the HSFCA permit program, to authorize high seas fishing activities. However, by continuing to require the separate HSFCA permit, NMFS is able to maintain a separate record of vessels

permitted to fish on the high seas, facilitating NMFS' ability to submit information regarding U.S. high seas vessels to the FAO as required under the Compliance Agreement. FAO compiles records of vessels authorized to fish on the high seas submitted by the Parties to the Compliance Agreement. The separate HSFCA permit, required under the existing regulations to be carried on board the vessel, is also useful in demonstrating to any domestic inspectors, foreign inspectors operating under the authority of a high seas boarding and inspection scheme adopted by an RFMO to which the United States is party, or foreign port inspectors, that a vessel is permitted to fish on the high seas.

With respect to the EMTU requirement, one alternative would be to require EMTU operation at all times, which would provide NMFS the ability to monitor a vessel's location at any time. However, NMFS is aware that some vessels holding high seas fishing permits may remain in the EEZ for extended periods and are not currently subject to EMTU operation requirements while in the EEZ. Some of these vessels may also dock their vessels and not engage in fishing for portions of the year. This alternative is not preferred because the regulatory burden could be minimized by providing some exemptions to the EMTU operation requirement, such as exemptions to address the two circumstances described above. The preferred alternative would maintain the ability to monitor high seas fishing vessels yet minimize the regulatory burden.

Another alternative would be to require EMTU operation only on the high seas. However, allowing units to be powered down while a vessel is in the EEZ of the U.S. for less than the allotted exemption time or in the EEZ of another country would weaken the effectiveness of using EMTU position information to monitor the locations of high seas fishing vessels. For vessels that are highly mobile and could operate at any time of the year, such as many high seas fishing vessels, EMTUs are more effective if they remain in operation at all times. Allowing power-downs whenever in the EEZ, in addition to the in-port and long-term exemptions provided in the proposed rule, could also encourage non-compliance and result in large gaps in NMFS' ability to monitor high seas fishing vessels. Thus, this alternative is not preferred.

With respect to the requirement for prior notice of high seas transshipments, one alternative would be to allow affected entities to provide the notice of high seas transshipment to NMFS at

least one business day in advance of the transshipment, rather than 36 hours as proposed. However, a shorter advance notice would reduce opportunities for NMFS or the U.S. Coast Guard to observe transshipments in the event they are able to meet the transshipping vessels at sea. For this reason, this alternative is not preferred.

With respect to the transshipment reporting requirements, one alternative would be to impose a different timeframe for submission of the report. The report could be submitted more than 15 days after completion of the transshipment. However, NMFS believes 15 days is a reasonable timeframe, and that extending it further could lead to NMFS not receiving transshipment reports in a timely manner and would not support collection of complete information regarding authorized fisheries.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a letter to permit holders that also serves as small entity compliance guide (the guide) was prepared. Copies of this final rule are available from the NMFS Office for International Affairs and Seafood Inspection, and the guide, *i.e.*, permit holder letter, will be sent to all HSFCA permit holders. The guide and this final rule will be available upon request.

National Environmental Policy Act

The provisions of this rule are administrative in nature and facilitate monitoring of all high seas fishing vessels. The requirements for the installation of VMS EMTUs on vessels, the carrying of observers, and the prior notice and reporting of transshipments on the high seas will facilitate monitoring of vessels and will not have any impacts on the human environment. Moreover, the final rule also includes procedures that incorporate reviews under ESA and NEPA prior to any authorization of activities on the high seas. Therefore, this action is categorically excluded from further environmental review under NEPA pursuant to section 6.03.c.3(i) of NOAA Administrative Order 216-6.

Paperwork Reduction Act

This final rule contains a collection-of-information requirement approved by OMB under the Paperwork Reduction Act (PRA). This collection of information, under OMB Control No. 0648-0304, includes a permit application, vessel marking requirements, and high seas fishing effort and catch reporting. In addition to this collection of information, the final rule includes new requirements listed below.

The public reporting burden for each requirement has been estimated, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information per response. The estimates are as follows:

- Inclusion of a vessel photograph in the permit application: 30 minutes.
- Request for a fishery to be authorized on the high seas (optional): 110 hours.
- EMTU purchase and installation: 4 hours for purchase, installation, and activation of the EMTU and submittal of the installation and activation report.
- Position reports: Automatically sent by the EMTU.
- Notices of EMTU power-down and power-up: 10 minutes each.
- Prior notice for high seas transshipments: 15 minutes.
- Transshipment reporting: 1 hour.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

The reporting requirements described above amend an existing collection of information, (OMB Control No. 0648-0304) which has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

List of Subjects

50 CFR Part 300

Administrative practice and procedure, Confidential business information, Fisheries, Fishing, Fishing vessels, Foreign relations, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Statistics.

50 CFR Part 600

Administrative practice and procedure, Confidential business information, Fisheries, Fishing, Fishing

vessels, Foreign relations, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Statistics.

50 CFR Part 660

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaiian Natives, Indians, Northern Mariana Islands, Reporting and recordkeeping requirements.

50 CFR Part 665

Accountability measures, Annual catch limits, Fisheries, Fishing, Western and central Pacific.

Dated: October 9, 2015.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 300, 600, 660 and 665 are amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*, 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 5501 *et seq.*, 16 U.S.C. 2431 *et seq.*, 31 U.S.C. 9701 *et seq.*

Subpart B—[Removed and Reserved]

■ 2. Remove and reserve subpart B, consisting of § 300.10 through 300.17.

■ 3. Add subpart Q to read as follows:

Subpart Q—High Seas Fisheries

Sec.	
300.330	Purpose.
300.331	Definitions.
300.332	Issuing offices.
300.333	Vessel permits.
300.334	Fisheries authorized on the high seas.
300.335	Bottom fishing.
300.336	Vessel identification.
300.337	Requirements for Enhanced Mobile Transceiver Units (EMTUs).
300.338	Observers.
300.339	Transshipment on the high seas.
300.340	Prohibitions.
300.341	Reporting.

Subpart Q—High Seas Fisheries

Authority: 16 U.S.C. 5501 *et seq.*

§ 300.330 Purpose.

This subpart implements the High Seas Fishing Compliance Act of 1995 (Act), which requires the Secretary to license U.S. vessels fishing on the high seas and to ensure that such vessels do not operate in contravention of international conservation and

management measures recognized by the United States.

§ 300.331 Definitions.

In addition to the terms defined in section 300.2 and those in the Act and the Agreement to Promote Compliance with International Conservation and Management Measures by Fishing Vessels on the High Seas, adopted by the Conference of the Food and Agriculture Organization of the United Nations on November 24, 1993 (Agreement), the terms used in this subpart have the following meanings. If a term is defined differently in section 300.2, the Act, or the Agreement, the definition in this section shall apply.

Bottom fishing means fishing using gear that is likely to contact the seafloor during the normal course of fishing operations.

Enhanced mobile transceiver unit (EMTU) is defined in 50 CFR 600.1500.

High seas means the waters beyond the territorial sea or exclusive economic zone (or the equivalent) of any Nation, to the extent that such territorial sea or exclusive economic zone (or the equivalent) is recognized by the United States.

High seas fishing permit means a permit issued under this subpart.

High seas fishing vessel means any vessel of the United States used or intended for use on the high seas for the purpose of the commercial exploitation of living marine resources and as a harvesting vessel, mothership, or any other support vessel directly engaged in a fishing operation. Support vessels include vessels that process or transship fish on the high seas; provide supplies, personnel or fuel on the high seas to other fishing vessels; or conduct other activities in support of, or in preparation for fishing.

International conservation and management measures means measures to conserve or manage one or more species of living marine resources that are adopted and applied in accordance with the relevant rules of international law, as reflected in the 1982 United Nations Convention on the Law of the Sea, and that are recognized by the United States. Such measures may be adopted by global, regional, or sub-regional fisheries organizations, subject to the rights and obligations of their members, or by treaties or other international agreements.

Observer means any person serving in the capacity of an observer employed by NMFS, either directly or under contract with a third party, or certified as an observer by NMFS.

Office Director means the director of the NMFS Office for International Affairs and Seafood Inspection.

Regional Administrator means any one of the Directors of a NMFS regional office, defined under § 300.2.

Transship or transshipment means offloading or receiving or otherwise transferring fish or fish products from one fishing vessel to another. Excluded from this definition is net sharing, which means the transfer of fish that have not yet been loaded on board any fishing vessel from the purse seine net of one vessel to another fishing vessel. Fish shall be considered to be on board a fishing vessel once they are on a deck or in a hold, or once they are first lifted out of the water by the vessel.

Vessel monitoring system (VMS) is defined in 50 CFR 600.1500.

§ 300.332 Issuing offices.

Any Regional Administrator or the Office Director may issue permits required under this subpart. While applicants for permits may submit an application to any Regional Administrator or the Office Director, applicants are encouraged to submit their applications (with envelopes marked "Attn: HSFCA Permits") to the Regional Administrator or the Office Director with whom they normally interact on fisheries matters.

§ 300.333 Vessel permits.

(a) **Eligibility.** (1) Any vessel owner or operator of a high seas fishing vessel is eligible to receive a permit for a fishery authorized on the high seas under this subpart, unless the vessel was previously authorized to be used for fishing on the high seas by a foreign nation, and—

(i) The foreign nation suspended such authorization, because the vessel undermined the effectiveness of international conservation and management measures, and the suspension has not expired; or

(ii) The foreign nation, within the 3 years preceding application for a permit under this section, withdrew such authorization, because the vessel undermined the effectiveness of international conservation and management measures.

(2) The restrictions in paragraphs (a)(1)(i) and (ii) of this section do not apply if ownership of the vessel has changed since the vessel undermined the effectiveness of international conservation and management measures, and the new owner has provided sufficient evidence to the Regional Administrator or Office Director demonstrating that the owner and operator at the time the vessel

undermined the effectiveness of such measures have no further legal, beneficial, or financial interest in, or control of, the vessel.

(3) The restrictions in paragraphs (a)(1)(i) and (ii) of this section do not apply if it is determined by the Regional Administrator or Office Director that issuing a permit would not subvert the purposes of the Agreement.

(b) *Applicability.* Any high seas fishing vessel used for fishing, as defined under § 300.2, on the high seas must have on board a valid permit issued under this subpart.

(c) *Application.* Permit application forms are available from the NMFS Web site or from any Regional Administrator or the Office Director. Failure to submit a complete and accurate application, along with all other required documentation and the specified fee will preclude issuance of a permit. To apply for a permit under this subpart, the owner or operator of a high seas fishing vessel must submit the following to a Regional Administrator or Office Director:

(1) A complete, accurate application form signed by the vessel owner or operator.

(2) Information required under this section and § 300.334(a).

(3) A color photograph showing an entire bow-to-stern side-view of the vessel in its current form and appearance. The photograph must clearly and legibly display the vessel name and identification markings. If the vessel's form or appearance materially changes (such as the vessel is painted another color, the vessel's identification markings change, or the vessel undergoes a structural modification) the vessel owner and operator must submit a new photograph of the vessel within 15 days of the change.

(4) For vessels with state registration instead of U.S. Coast Guard documentation, the applicant must supply additional vessel information that NMFS may request.

(5) The fee specified in the application form. Payment by a commercial instrument later determined to be insufficiently funded will invalidate any permit. NMFS charges this fee to recover the administrative expenses of permit issuance, and the amount of the fee is determined in accordance with the procedures of the NOAA Finance Handbook.

(d) *Permit issuance and validity.* (1) Except as provided for in subpart D of 15 CFR part 904, and subject to paragraphs (a), (c), and (d)(2) and (3) of this section, the Regional Administrator or Office Director will issue a permit, which will include applicable

conditions or restrictions, within 15 days of receipt of a completed application and payment of the appropriate fee.

(2) The Regional Administrator or Office Director will not issue a permit unless an EMTU has been installed and activated on the vessel in accordance with § 300.337(c)(2).

(3) The Regional Administrator or Office Director will not issue a permit unless the applicant holds a valid permit for the subject vessel for any U.S. domestic fisheries related to the authorized high seas fishery.

(4) Except as otherwise provided, permits issued under this subpart are valid for 5 years from the date of issuance. For a permit to remain valid to its expiration date, the vessel's U.S. Coast Guard documentation or state registration must be kept current. A permit issued under this subpart is void when the vessel owner or the name of the vessel changes, or in the event the vessel is no longer eligible for U.S. documentation, such documentation is revoked or denied, or the vessel is removed from such documentation.

(5) A permit issued under this subpart is not transferable or assignable to another vessel or owner; it is valid only for the vessel and owner to which it is issued.

(e) *Display.* A valid permit, or a copy thereof, issued under this subpart must be on board any high seas fishing vessel while operating on the high seas and available for inspection by an authorized officer.

(f) *Change in application information.* Any changes in vessel documentation status or other permit application information must be reported in writing to the Regional Administrator or Office Director who issued the permit within 15 days of such changes.

(g) *Renewal.* Application for renewal of a permit prior to its expiration is the responsibility of the permit holder and may be completed per § 300.333(c). The Regional Administrator or Office Director will not consider a permit renewal application to be complete until the permit holder satisfies all required fishing activity report requirements under the permit and § 300.341. The Regional Administrator or Office Director will not issue a renewed permit unless an EMTU has been activated on the vessel in accordance with § 300.337(c)(2) and the applicant holds a valid permit for the subject vessel for any U.S. domestic fisheries related to the authorized high seas fishery.

(h) *Marine mammals and ESA-listed species.* Permits issued under this section do not authorize vessels or persons subject to the jurisdiction of the

United States to take marine mammals or ESA-listed species. No marine mammals or ESA-listed species may be taken in the course of fishing operations unless the taking is allowed under the Marine Mammal Protection Act or the Endangered Species Act (ESA), pursuant to regulations, an authorization, or permit granted by NMFS or the U.S. Fish and Wildlife Service.

(i) *Permit Status Changes.* NMFS may modify, suspend, or revoke a permit issued under this subpart if permitted activities may impact living marine resources in ways that were not considered at the time of permit issuance; are in contravention of an international conservation and management measure; or violate any applicable law. NMFS will notify an affected permit holder of any potential change in permit status by contacting the permit holder at the address of record provided on the permit application or as updated pursuant to paragraph (f) of this subsection and will provide an opportunity to respond, consistent with the Administrative Procedure Act and other applicable law.

§ 300.334 Fisheries authorized on the high seas.

(a) *General.* When applying for a permit under § 300.333, the owner or operator of a high seas fishing vessel must identify in the application the authorized fisheries in which he or she intends to fish. More than one authorized fishery may be selected. The following fisheries are authorized on the high seas:

(1) 50 CFR part 300, subpart C—Eastern Pacific Tuna Fisheries.

(2) 50 CFR part 300, subpart D—South Pacific Tuna Fisheries.

(3) 50 CFR part 300, subpart G—Antarctic Marine Living Resources.

(4) 50 CFR part 635—Atlantic Highly Migratory Species Fisheries.

(5) 50 CFR part 660, subpart K—U.S. West Coast Fisheries for Highly Migratory Species.

(6) 50 CFR part 665, subpart F—Western Pacific Pelagic Fisheries.

(7) South Pacific Albacore Troll Fishery.

(8) Northwest Atlantic Fishery.

(b) *Requirements for authorized fisheries.* For each of the authorized fisheries specified on the high seas fishing permit, the owner or operator of the high seas fishing vessel must:

(1) Abide by the regulations, set forth in other parts of this chapter and Chapter VI, governing those authorized fisheries while operating on the high seas;

(2) Obtain and renew any appropriate permits or authorizations; and

(3) Notify the Regional Administrator or Office Director who issued the permit immediately in the event that a species listed as threatened or endangered under the ESA is taken incidental to the fishing activities without authorization under a relevant incidental take statement.

(c) *Change in authorized fisheries.* If a high seas fishing permit holder elects to change the authorized fisheries specified on the permit, he or she shall notify the Regional Administrator or Office Director who issued the permit of the change(s) and shall obtain the underlying permits for the authorized fisheries prior to engaging in the fishery on the high seas. Per the process under § 300.333(d), the Regional Administrator or Office Director will then issue a revised high seas fishing permit which will expire 5 years from the original effective date.

(d) *Revision of authorized fisheries list.* Through rulemaking, NMFS will add a fishery to, or delete a fishery from, the list in paragraph (a) of this section. NMFS may add or delete fisheries from the list after completing any analyses required under the Endangered Species Act, Marine Mammal Protection Act, National Environmental Policy Act, and other applicable laws. In taking such action, NMFS, in consultation with the relevant Regional Fishery Management Council(s) where appropriate, will consider, among other things, whether:

(1) The proposed fishing activities would detrimentally affect the well-being of the stock of any regulated species of fish, marine mammal, or species listed as threatened or endangered under the Endangered Species Act;

(2) The proposed fishing activities would be inconsistent with relevant fishery management plans and their implementing regulations or other applicable law;

(3) Insufficient mechanisms exist to effectively monitor the activities of vessels engaged in the proposed fishing activities; or

(4) The proposed fishing activities would contravene international conservation and management measures recognized by the United States.

(e) *Request for revision of authorized fisheries list.* A person may submit a written request to the Office Director to add a fishery to or delete a fishery from the list. A request to delete a fishery from the list of authorized fisheries must include the name of the fishery; information that addresses considerations under paragraph (d) of this section; and, if requested by NMFS, any additional information necessary for NMFS to conduct analyses required

under applicable laws. A request to add a fishery to the list of authorized fisheries must include the following information:

(1) The species (target and incidental) expected to be harvested and the anticipated amounts of such harvest and bycatch;

(2) The approximate times and places when fishing is expected to take place, the number and type of vessels expected to participate, and the type, size, and amount of gear expected to be used;

(3) A description of the specific area that may be affected by the fishing activities;

(4) A description of any anticipated impacts on the environment, including impacts on fisheries, marine mammals, and species listed as threatened or endangered under the ESA or their critical habitat;

(5) Other information that addresses considerations under paragraph (d) of this section; and

(6) If requested by NMFS, any additional information necessary for NMFS to conduct analyses required under applicable laws.

(7) Once all required information is received to proceed with consideration of a request, NMFS will publish in the **Federal Register** a proposed rule, noting receipt of the request to add an authorized fishery, and inviting information and comments. Relevant information received during the comment period may be considered by NMFS and, where appropriate, the relevant Regional Fishery Management Council(s), in analyzing potential environmental impacts of the fisheries and developing any conditions or restrictions. Based on its analysis, considerations under paragraph (d) of this section, and other relevant considerations, NMFS will publish its decision on the request in the **Federal Register**.

(f) *Deletion of a fishery from the authorized fisheries list.* NMFS will delete (*i.e.*, deauthorize) a fishery under paragraph (d) or (e) of this section through publication of a final rule. NMFS will also provide notice to affected permit holders by email and by Registered Mail at the addresses provided to NMFS in the high seas permit application. When a fishery is deleted from the list, any activities on the high seas related to that fishery are prohibited as of the effective date of the final rule. In addition, the high seas permit will be voided unless the permit holder notifies NMFS that he or she elects to change to another authorized high seas fishery or continue in any other authorized fisheries noted on the permit. Once the applicant so notifies

NMFS and, if necessary, secures any underlying permits necessary for participation in another authorized high seas fishery, the Regional Administrator or Office Director will then issue a revised high seas fishing permit per the process under § 300.333(d). The revised permit will expire 5 years from the original effective date.

§ 300.335 Bottom fishing.

(a) Bottom fishing may be permitted on the high seas when authorized by international conservation and management measures recognized by the United States. For bottom fishing activity not subject to international conservation measures recognized by the United States, a person who seeks to engage in such fishing must request authorization of a new high seas fishery as described in § 300.334(e) and then, if the fishery is authorized, must obtain all applicable permits including a high seas fishing permit issued under § 300.333. NMFS may specify conditions and restrictions in the permit to mitigate adverse impacts on VMEs, which may include the types of conditions that have been adopted in relevant RFMO measures recognized by the United States.

(b) *Permit.* To be permitted under this section, the owner or operator of a high seas fishing vessel must follow the procedures under § 300.334(e) or, if he or she seeks to change an existing permit, must follow the procedures under § 300.334(c).

§ 300.336 Vessel identification.

(a) *General.* A vessel permitted under this subpart must be marked for identification purposes in accordance with this section.

(b) *Marking.* Vessels must be marked either:

(1) In accordance with vessel identification requirements specified in Federal fishery regulations issued under the Magnuson-Stevens Act or under other Federal fishery management statutes; or

(2) In accordance with the following identification requirements:

(i) A vessel must be marked with its international radio call sign (IRCS) or, if not assigned an IRCS, must be marked (in order of priority) with its Federal, state, or other documentation number appearing on its high seas fishing permit and, if a WCPFC Area Endorsement has been issued for the vessel under § 300.212, that documentation number must be preceded by the characters "USA" and a hyphen (that is, "USA-");

(ii) The markings must be displayed at all times on the vessel's side or

superstructure, port and starboard, as well as on a deck;

(iii) The markings must be placed so that they do not extend below the waterline, are not obscured by fishing gear, whether stowed or in use, and are clear of flow from scuppers or overboard discharges that might damage or discolor the markings;

(iv) Block lettering and numbering must be used;

(v) The height of the letters and numbers must be in proportion to the size of the vessel as follows: for vessels 25 meters (m) and over in length overall, the height of letters and numbers must be no less than 1.0 m; for vessels 20 m but less than 25 m in length overall, the height of letters and numbers must be no less than 0.8 m; for vessels 15 m but less than 20 m in length overall, the height of letters and numbers must be no less than 0.6 m; for vessels 12 m but less than 15 m in length overall, the height of letters and numbers must be no less than 0.4 m; for vessels 5 m but less than 12 m in length overall, the height of letters and numbers must be no less than 0.3 m; and for vessels under 5 m in length overall, the height of letters and numbers must be no less than 0.1 m;

(vi) The height of the letters and numbers to be placed on decks must be no less than 0.3 m;

(vii) The length of the hyphen(s), if any, must be half the height (h) of the letters and numbers;

(viii) The width of the stroke for all letters, numbers, and hyphens must be $h/6$;

(ix) The space between letters and/or numbers must not exceed $h/4$ nor be less than $h/6$;

(x) The space between adjacent letters having sloping sides must not exceed $h/8$ nor be less than $h/10$;

(xi) The marks must be white on a black background, or black on a white background;

(xii) The background must extend to provide a border around the mark of no less than $h/6$; and

(xiii) The marks and the background must be maintained in good condition at all times.

§ 300.337 Requirements for Enhanced Mobile Transceiver Units (EMTUs).

(a) *Vessel position information.* The owner or operator of a vessel issued a permit under this subpart, or for which such permit is required, must have installed on board the vessel a NMFS type-approved enhanced mobile transceiver unit (EMTU). The operator or owner of the vessel must ensure that the EMTU is operational and properly reporting positions to NMFS as required

by this section, except when exempt under paragraph (d)(1) or (2) of this section. If the vessel is also subject to EMTU requirements in other parts of this title, the more restrictive requirements apply.

(b) *Contact information and business hours.* With respect to the requirements in this section, vessel owners and operators should consult with the divisional office of the NOAA Office of Law Enforcement (OLE) in, or nearest, the Region issuing the permit under this subpart. The OLE VMS Helpdesk in OLE headquarters office may also be contacted.

(c) *EMTU installation and activation*—(1) *EMTU installation.* The vessel owner or operator shall obtain and have installed on the fishing vessel, by a qualified marine electrician and in accordance with any instructions provided by the VMS Helpdesk or OLE divisional office, a NMFS type-approved EMTU. OLE is authorized to receive and relay transmissions from the EMTU. The vessel owner and operator shall arrange for a type-approved mobile communications service to receive and transmit position reports and email communications from the EMTU to OLE. NMFS makes available lists of type-approved EMTUs and mobile communications service providers. Vessel owners must ensure that the EMTU and communications service hardware purchased is type-approved for all fisheries and regions in which their vessel will be operating.

(2) *EMTU activation.* When an EMTU is installed or reinstalled or the mobile communications service provider changes, or if directed by OLE, the vessel owner and operator shall, prior to leaving port:

(i) Turn on the EMTU to make it operational;

(ii) Submit a VMS Installation and Activation Certification form, or an activation report as directed by OLE, to the OLE divisional office within or nearest to the region issuing the permit under this subpart; and

(iii) Receive confirmation from OLE that transmissions are being received properly from the EMTU.

(d) *EMTU operation.* Unless otherwise provided below, and subject to more restrictive requirements where applicable, the vessel owner or operator shall continuously operate the EMTU so that it automatically transmits position information to OLE, once every hour or as directed by OLE.

(1) *In-port exemption:* The EMTU may be powered down when the vessel will remain at a dock or permanent mooring for more than 72 consecutive hours and after the notice required in paragraph

(d)(3) of this section is submitted to OLE. When powering up the EMTU after the in-port exemption, the vessel owner or operator must submit the report required in paragraph (d)(4) of this section at least 2 hours before leaving port or mooring.

(2) *Long-term exemption:* The EMTU may be powered down if the vessel will not operate on the high seas, or in any fishery that requires EMTU operation, for more than 30 consecutive days and after the notice required in paragraph (d)(3) of this section is submitted. When powering up the EMTU from the long-term exemption, the vessel owner or operator must submit the report required in paragraph (d)(4) of this section.

(3) Prior to each power-down of the EMTU, under paragraph (d)(1) or (2) of this section, the vessel owner or operator must report to the OLE divisional office in, or nearest, the Region issuing the permit under this subpart during business hours, via email or other means as directed by OLE: the vessel's name; the vessel's official number; the intent to power down the EMTU; the reason for power-down; the port where the vessel is docked or area where it will be operating; and the full name, telephone, and email contact information for the vessel owner or operator.

(4) When powering up the EMTU, the vessel owner or operator must report to the OLE divisional office in, or nearest, the Region issuing the permit under this subpart during business hours, via email or other means as directed by OLE: The fact that the EMTU has been powered up; the vessel's name; the vessel's official number; port name; intended fishery; and full name, telephone, and email contact information for the vessel owner or operator.

(5) If the EMTU is powered up after a long-term or in-port exemption, the vessel owner must receive confirmation from the OLE divisional office in, or nearest, the Region issuing the permit under this subpart that EMTU transmissions are being received properly before leaving port, entering the high seas, or entering a fishery that requires EMTU operation.

(e) *Failure of EMTU.* If the vessel owner or operator becomes aware that the EMTU has become inoperable or that transmission of automatic position reports from the EMTU has been interrupted, or if notified by OLE or the U.S. Coast Guard that automatic position reports are not being received from the EMTU or that an inspection of the EMTU has revealed a problem with the performance of the EMTU, the

vessel owner or operator shall comply with the following requirements:

(1) If the vessel is in port, the vessel owner or operator shall repair or replace the EMTU and comply with the requirements in paragraph (c)(2) of this section before the vessel leaves port.

(2) If the vessel is at sea, the vessel owner, operator, or designee shall contact the OLE divisional office in, or nearest, the Region issuing the permit under this subpart by telephone or email at the earliest opportunity during business hours and identify the caller, vessel name, vessel location, and the type of fishing permit(s). The vessel operator shall follow the instructions provided by the OLE divisional office, which could include: Ceasing fishing, stowing fishing gear, returning to port, or submitting periodic position reports at specified intervals by other means. The vessel owner or operator must repair or replace the EMTU and comply with the requirements in paragraph (c)(2) of this section within 30 days or before the vessel leaves port, whichever is sooner.

(f) *Related VMS requirements.* Unless specified otherwise in the high seas fishing permit, a vessel owner's and operator's compliance with requirements in part 300, 635, 660, or 665 of this title relating to the installation, carrying, and operation of EMTUs will satisfy the requirements of this section, if the requirements are the same or more restrictive than those in this section and provided that:

(1) On the high seas, the EMTU is operated continuously and position information is automatically transmitted a minimum of once every hour;

(2) The EMTU is type-approved by NMFS;

(3) OLE is authorized to receive and relay transmissions from the EMTU; and

(4) The requirements of paragraph (d) of this section are complied with. If the EMTU is owned by NMFS, the requirement under paragraph (e) of this section to repair or replace the EMTU will be the responsibility of NMFS, but the vessel owner and operator shall be responsible for ensuring that the EMTU complies with the requirements specified in paragraph (c)(2) of this section before the vessel leaves port.

(g) *Costs.* The vessel owner and operator shall be responsible for all costs associated with the purchase, installation, operation, and maintenance of the EMTU and for all charges levied by vendors as necessary to ensure the transmission of automatic position reports to OLE as required in paragraph (c) of this section. However, if the EMTU is being carried and operated in compliance with the requirements in

part 300, 635, 660, or 665 of this title relating to the installation, carrying, and operation of EMTUs, the vessel owner and operator shall not be responsible for any costs that are the responsibility of NMFS under those regulations.

(h) *Tampering.* The vessel owner and operator shall ensure that the EMTU is not tampered with, disabled, destroyed, damaged or operated improperly, and that its operation is not impeded or interfered with.

(i) *Inspection.* The vessel owner and operator shall make the EMTU, including its antenna, connectors and antenna cable, available for inspection by authorized officers or by officers conducting boarding and inspection under a scheme adopted by an RFMO of which the United States is a member.

(j) *Access to data.* As required under fishery-specific regulations in other parts of this title, the vessel owner and operator shall make the vessel's position data, obtained from the EMTU or other means, available to authorized officers and to any inspector conducting a high seas boarding and inspection pursuant to a scheme adopted by an RFMO of which the United States is a member.

(k) *Communication devices.* In cases of EMTU failure as specified under paragraph (e) of this section, and to facilitate communication with management and enforcement authorities regarding the functioning of the EMTU and other purposes, the vessel operator shall, while the vessel is at sea, carry on board and continuously monitor a two-way communication device, in addition to the EMTU, that is capable of real-time communication with the OLE divisional office in, or nearest, the Region issuing the permit under this subpart.

§ 300.338 Observers.

(a) Where observer coverage is not otherwise required by other regulations or relevant RFMO conservation and management measures, NMFS may select for at-sea observer coverage any vessel that has been issued a high seas fishing permit. A vessel so selected by NMFS must carry an observer when directed to do so.

(b) NMFS will contact a vessel owner, in writing, when his or her vessel is selected for observer coverage under this section.

(c) A vessel shall not fish on the high seas without taking an observer if NMFS contacted the vessel owner under paragraph (b) of this section, or if so required as a condition of a permit issued under this subpart or pursuant to other legal authorities, unless the requirement to carry an observer has

been waived under paragraph (d) of this section.

(d) The vessel owner that NMFS contacts under paragraph (b) of this section must notify NMFS of his or her next fishing trip that may take place on the high seas before commencing the fishing trip. NMFS will specify the notification procedures and information requirements, such as expected gear deployment, trip duration and fishing area, in its selection letter. Once notified of a trip by the vessel owner, NMFS will assign an observer for that trip or notify the vessel owner that coverage pursuant to this subpart is not required, given the existing requirement for observer coverage under other legal authorities.

(e) The owner, operator, and crew of a vessel on which a NMFS-approved observer is assigned must comply with safety regulations at §§ 600.725 and 600.746 of this title and—

(1) Facilitate the safe embarkation and debarkation of the observer.

(2) Provide the observer with accommodations, food, and amenities that are equivalent of those provided to vessel officers.

(3) Allow the observer access to all areas of the vessel necessary to conduct observer duties.

(4) Allow the observer free and unobstructed access to the vessel's bridge, working decks, holding bins, weight scales, holds, and any other space used to hold, process, weigh, or store fish.

(5) Allow the observer access to EMTUs, communications equipment, and navigation equipment to verify operation, obtain data, and use the communication capabilities of the units for official purposes.

(6) Allow the observer to inspect and copy the vessel's log, communications logs, and any records associated with the catch and disposition of fish for that trip.

(7) Provide accurate vessel locations by latitude and longitude upon request by the observer.

(8) Provide access to sea turtle, marine mammal, sea bird, or other specimens as requested by the observer.

(9) Notify the observer in a timely fashion when commercial fishing activity is to begin and end.

(f) The permit holder, vessel operator, and crew must cooperate with the observer in the performance of the observer's duties.

(g) The permit holder, vessel operator, and crew must comply with other terms and conditions to ensure the effective deployment and use of observers that the Regional Administrator or Office Director imposes by written notice.

§ 300.339 Transshipment on the high seas.

(a) In addition to any other applicable restrictions on transshipment, including those under parts 300 and 635 of this title, the following requirements apply to transshipments, when authorized, taking place on the high seas:

(1) The owner or operator of a U.S. vessel receiving or offloading fish on the high seas shall provide a notice by fax or email to the Regional Administrator or the Office Director at least 36 hours prior to any intended transshipment on the high seas with the following information: the vessels offloading and receiving the transshipment (names, official numbers, and vessel types); the location (latitude and longitude to the nearest tenth of a degree) of transshipment; date and time that transshipment is expected to occur; and species, processed state, and quantities (in metric tons) expected to be transshipped. If another requirement for prior notice applies, the more restrictive requirement (*i.e.*, a requirement for greater advance notice and/or more specific information regarding vessels, location etc.) must be followed.

(2) U.S. high seas fishing vessels shall report transshipments on the high seas to the Regional Administrator or Office Director within 15 calendar days after the vessel first enters into port, using the form obtained from the Regional Administrator or Office Director. If there are applicable transshipment reporting requirements in other parts of this title, the more restrictive requirement (*e.g.*, a reporting requirement of fewer than 15 calendar days) must be followed.

(b) [Reserved]

§ 300.340 Prohibitions.

In addition to the prohibitions in § 300.4, it is unlawful for any person to:

(a) Use a high seas fishing vessel on the high seas in contravention of international conservation and management measures.

(b) Fish on the high seas unless the vessel has been issued, and has on board, a valid permit issued under § 300.333(d).

(c) Fish on the high seas unless the vessel has been issued, and has on board, valid permits related to the authorized fisheries noted on the high seas fishing permit, as required under § 300.334(b).

(d) Operate a high seas fishing vessel on the high seas that is not marked in accordance with § 300.336.

(e) With respect to the EMTU,

(1) Fail to install, activate, or continuously operate a properly functioning and type-approved EMTU as required in § 300.337;

(2) Power-down or power-up the EMTU without following the procedures required in § 300.337;

(3) In the event of EMTU failure or interruption, fail to repair or replace an EMTU, fail to notify the appropriate OLE divisional office and follow the instructions provided, or otherwise fail to act as required in § 300.337;

(4) Disable, destroy, damage or operate improperly an EMTU installed under § 300.337, attempt to do any of the same, or fail to ensure that its operation is not impeded or interfered with, as provided in § 300.337;

(5) Fail to make an EMTU installed under § 300.337 or the position data obtained from it available for inspection, as provided in § 300.337; or

(6) Fail to carry on board and monitor communication devices as required in § 300.337(l);

(f) With respect to observers,

(1) Fail to provide to an observer, a NMFS employee, or a designated observer provider, information that has been requested pursuant to § 300.338 or § 600.746 of this title, or fail to allow an observer, a NMFS employee, or a designated observer provider to inspect any item described at § 300.338 or § 600.746 of this title;

(2) Fish without an observer when the vessel is required to carry an observer pursuant to § 300.338(c);

(3) Assault, oppose, harass, impede, intimidate, or interfere with an observer;

(4) Prohibit or bar by command, impediment, threat, coercion, interference, or refusal of reasonable assistance, an observer from conducting his or her duties as an observer; or

(5) Tamper with or destroy samples or equipment.

(g) Fail to submit a prior notice or a report of a transshipment as provided in § 300.339(b) of this title.

(h) Fail to comply with reporting requirements as provided in § 300.341.

§ 300.341 Reporting.

(a) *General.* The operator of any vessel permitted under this subpart must accurately maintain on board the vessel a complete record of fishing activities, such as catch, effort, and other data and report high seas catch and effort information to NMFS in a manner consistent with the reporting requirements of the authorized fishery(ies) noted on the high seas permit. Reports must include: identification information for vessel and operator; operator signature; crew size; whether an observer is aboard; target species; gear used; dates, times, locations, and conditions under which fishing was conducted; species and amounts of fish retained and discarded;

and details of any interactions with sea turtles, marine mammals, or birds.

(1) The vessel owner and operator are responsible for obtaining and completing the reporting forms from the Regional Administrator or Office Director who issued the permit holder's high seas fishing permit. The completed forms must be submitted to the same Regional Administrator or Office Director or, if directed by NMFS, to a Science Center.

(2) Reports must be submitted within the deadline provided for in the authorized fishery or within 15 days following the end of a fishing trip, whichever is sooner. Contact information for the Regional Administrators and Science Center Directors can be found on the NMFS Web site.

(b) [Reserved]

PART 600—MAGNUSON-STEVENS ACT PROVISIONS

■ 4. The authority citation for part 600 continues to read as follows:

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

■ 5. In § 600.705, add paragraph (g) to read as follows:

§ 600.705 Relation to other laws.

* * * * *

(g) *High seas fishing activities.* Regulations governing permits and requirements for fishing activities on the high seas are set forth in 50 CFR part 300, subparts A and Q. Any vessel operating on the high seas must obtain a permit issued pursuant to the High Seas Fishing Compliance Act.

■ 6. In § 600.745, revise the first two sentences in paragraph (a) to read as follows:

§ 600.745 Scientific research activity, exempted fishing, and exempted educational activity.

(a) *Scientific research activity.* Nothing in this part is intended to inhibit or prevent any scientific research activity conducted by a scientific research vessel. Persons planning to conduct scientific research activities on board a scientific research vessel in the EEZ or on the high seas are encouraged to submit to the appropriate Regional Administrator or Director, 60 days or as soon as practicable prior to its start, a scientific research plan for each scientific activity.* * *

* * * * *

PART 660—FISHERIES OFF WEST COAST STATES

■ 7. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 773 *et seq.*, and 16 U.S.C. 7001 *et seq.*

■ 8. In § 660.2, add paragraph (c) to read as follows:

§ 660.2 Relation to other laws.

* * * * *

(c) Fishing activities on the high seas are governed by regulations of the High Seas Fishing Compliance Act set forth in 50 CFR part 300, subparts A and Q.

§ 660.708 [Amended]

■ 9. In § 660.708, remove paragraph (a)(1)(iii) and redesignate paragraph (a)(1)(iv) as paragraph (a)(1)(iii).

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 10. The authority citation for part 665 continues to read as follows:

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

■ 11. In § 665.1, revise paragraph (b) to read as follows:

§ 665.1 Purpose and scope.

* * * * *

(b) General regulations governing fishing by all vessels of the United States and by fishing vessels other than vessels of the United States are contained in 50 CFR parts 300 and 600.

* * * * *

[FR Doc. 2015–26398 Filed 10–15–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 130403320–4891–02]

RIN 0648–XE245

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Resources of the South Atlantic; Trip Limit Reduction for Gag Grouper

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

ACTION: Temporary rule; trip limit reduction.

SUMMARY: NMFS reduces the commercial trip limit for gag grouper

(gag) in or from the exclusive economic zone (EEZ) of the South Atlantic to 500 lb (227 kg), gutted weight. This trip limit reduction is necessary to protect the South Atlantic gag resource.

DATES: This rule is effective 12:01 a.m., local time, October 18, 2015, until 12:01 a.m., local time, January 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: mary.vara@noaa.gov.

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery in the South Atlantic includes gag and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The commercial ACL (commercial quota) for gag in the South Atlantic during the 2015 fishing year is 295,459 lb (134,018 kg), gutted weight, 348,642 lb (158,141 kg), round weight, as specified in 50 CFR 622.190(a)(7)(i).

Under 50 CFR 622.191(a)(7)(ii), NMFS is required to reduce the commercial trip limit for gag from 1,000 lb (454 kg), gutted weight, 1,180 lb (535 kg), round weight, to 500 lb (227 kg), gutted weight, 590 lb (268 kg), round weight, when 75 percent of the quota is reached or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register, as implemented by the final rule for Regulatory Amendment 14 to the FMP (79 FR 66316, November 7, 2014). Based on current data, NMFS has determined that 75 percent of the available gag commercial quota will be reached by October 18, 2015. Accordingly, NMFS is reducing the commercial trip limit for gag to 500 lb (227 kg), gutted weight, 590 lb (268 kg), round weight, in or from the South Atlantic EEZ at 12:01 a.m., local time, on October 18, 2015. This 500-lb (227-kg), gutted weight, 590-lb (268-kg), round weight, trip limit will remain in effect until either the commercial sector reaches its quota and the sector closes, or through the end of the current fishing year on December 31, 2015, whichever occurs first.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of South Atlantic gag and

is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.191(a)(7) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for Fisheries, NOAA (AA), finds that the need to immediately implement this commercial trip limit reduction constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), because prior notice and opportunity for public comment on this temporary rule is unnecessary and contrary to the public interest. Such procedures are unnecessary, because the rule establishing the trip limit reduction has already been subject to notice and comment, and all that remains is to notify the public of the reduced trip limit. The procedures are contrary to the public interest, because there is a need to immediately implement this action to protect the gag resource since the capacity of the fishing fleet allows for rapid harvest of the quota. Prior notice and opportunity for public comment on this action would require time and would increase the probability that the commercial sector could exceed the quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: October 13, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–26396 Filed 10–13–15; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 141021887–5172–02]

RIN 0648–XE223

Fisheries of the Exclusive Economic Zone Off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area; Correction

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

ACTION: Temporary rule; correction.

SUMMARY: The National Marine Fisheries Service (NMFS) is correcting a temporary rule that exchanged unused Community Development Quota (CDQ) for CDQ acceptable biological catch (ABC) reserves that published on October 5, 2015. The CDQ group that initiated this transfer was incorrect.

DATES: Effective October 16, 2015.

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

SUPPLEMENTARY INFORMATION:

Need for Correction

NMFS published the exchange of unused CDQ for CDQ ABC reserves on October 5, 2015. The document contained errors by incorrectly stating which CDQ group initiated the transfer. This correction will not affect the fishing operations. These corrections are necessary to provide the correct information on which CDQ group initiated the transfer in order to avoid confusion by fishery participants.

Correction

1. In the **Federal Register** of October 5, 2015, (80 FR 60073) in FR Doc. 2015–25291, on page 60073, column 3, paragraph 2, sentence 1 is corrected to state:

“The Norton Sound Economic Development Corporation has requested that NMFS exchange 568 mt of flathead sole and 210 mt of rock sole CDQ reserves for 778 mt of yellowfin sole CDQ ABC reserves under § 679.31(d).”

2. In the **Federal Register** of October 5, 2015, (80 FR 60073) in FR Doc. 2015–25291, on page 60074, columns 1–2, paragraph 1, sentence 3 is corrected to state:

“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 flatfish exchange by the Norton Sound Economic Development Corporation in the BSAI.”

Classification

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 correction amendment corrects an error identifying the CDQ group that initiated the transfer and does not change operating practices in the fisheries. Corrections should be made as soon as possible to avoid confusion for participants in the fisheries.

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.

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

Dated: October 13, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–26367 Filed 10–15–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 140918791–4999–02]

RIN 0648–XE180

Fisheries of the Exclusive Economic Zone Off Alaska; Reapportionment of the 2015 Gulf of Alaska Pacific Halibut Prohibited Species Catch Limits for the Trawl Deep-Water and Shallow-Water Fishery Categories; Correction

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

ACTION: Temporary rule; correction.

SUMMARY: The National Marine Fisheries Service (NMFS) is correcting a temporary rule that reapportioned halibut prohibited species catch limits in the Gulf of Alaska (GOA) that published on September 11, 2015. The table in the document contained errors.

DATES: Effective October 16, 2015.

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

SUPPLEMENTARY INFORMATION:

Need for Correction

NMFS published the reapportionment of the 2015 Gulf of Alaska Pacific halibut prohibited species catch limits for the trawl deep-water and shallow-water fishery categories on September 11, 2015. The table in the document contained errors in the July 1–September 1 row and the Subtotal January 20–October 1 row. This correction will not affect the fishing operations. These corrections are necessary to provide the correct 2015 halibut PSC apportionments and eliminate potential confusion for participants in the fisheries.

Correction

In the **Federal Register** of September 11, 2015, (80 FR 54737) in FR Doc. 2015–22934, on page 54738, Table 16 is corrected and reprinted in its entirety to read as follows:

TABLE 16—FINAL 2015 APPORTIONMENT OF PACIFIC HALIBUT PSC TRAWL LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES FISHERY AND THE SHALLOW-WATER SPECIES FISHERY CATEGORIES

[Values are in metric tons]

Season	Shallow-water	Deep-water ¹	Total
January 20–April 1	135	35	170
April 1–July 1	291	375	666
Subtotal of combined first and second season limit (January 20–July 1)	426	410	836

TABLE 16—FINAL 2015 APPORTIONMENT OF PACIFIC HALIBUT PSC TRAWL LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES FISHERY AND THE SHALLOW-WATER SPECIES FISHERY CATEGORIES—Continued

[Values are in metric tons]

Season	Shallow-water	Deep-water ¹	Total
July 1–September 1	176	352	528
September 1–October 1	132	Any remainder ..	132
Subtotal January 20–October 1	734	762	1,496
October 1–December 31 ²	264
Total	1,760

¹ Vessels participating in cooperatives in the Central GOA Rockfish Program will receive 191 mt of the third season (July 1 through September 1) deep-water species fishery halibut PSC apportionment.

² There is no apportionment between trawl shallow-water and deep-water species fishery categories during the fifth season (October 1 through December 31).

Classification

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 correction amendment corrects the unintentional transposition of the 3rd

season halibut apportionments between deep-water and shallow water fishery categories in Table 16 and does not change operating practices in the fisheries. Corrections should be made as soon as possible to avoid confusion for participants in the fisheries.

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.

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

Dated: October 13, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–26372 Filed 10–15–15; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 80, No. 200

Friday, October 16, 2015

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 27

[DHS–2014–0016]

Chemical Facility Anti-Terrorism Standards (CFATS) Appendix A

AGENCY: National Protection and Programs Directorate, Department of Homeland Security.

ACTION: Notice of public meeting.

SUMMARY: The Department of Homeland Security (DHS or the Department) invites public comment on the Appendix A Chemicals of Interest (COI) list. These comments may be used for potential revisions to the Chemical Facility Anti-Terrorism Standards (CFATS) regulations.

DATES: A roundtable discussion will be held from 8:30 a.m. to 12:00 p.m. followed by a listening session from 1:00 p.m. to 4:00 p.m. on Tuesday, October 27, 2015. Written comments must be submitted on or before Monday, November 30, 2015.

ADDRESSES: The roundtable discussion and public listening session will be held at:

- The National Training Center, 1310 North Courthouse Road, Suite 600, Arlington, VA 22201.

You may submit comments, identified by docket number DHS–2014–0016. To avoid duplication, please use only one of the following methods:

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

- *Mail:* U.S. Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Security Compliance Division, 245 Murray Lane, Mail Stop 0610, Arlington, VA 20528–0610.

- *In person:* Verbal comments are acceptable in person at the public listening session.

Registration to Attend and/or to Participate: If you wish to attend the roundtable discussion and public listening session and/or make an oral comment at the listening session, please register at <http://www.cvent.com/d/8rqbsg/4W>. If you cannot attend in person you may register to participate in a listen-only webinar. Comments will not be accepted during the webinar. Attendees of the webinar may submit written comments using the methods identified in this section. Please note that the morning portion will consist of a technical, roundtable discussion and the afternoon portion will consist of a listening session. There is no fee to register for either session. Same-day registration is permitted but seating will only be on a space-available basis, beginning at 7:30 a.m. We will do our best to accommodate all persons who wish to make a comment during the listening session. DHS encourages persons and groups having similar interests to consolidate their information for presentation through a single representative.

FOR FURTHER INFORMATION CONTACT: Jon MacLaren, Rulemaking Section Chief, Office of Infrastructure Protection, Infrastructure Security Compliance Division, 245 Murray Lane, Mail Stop 0610, Washington, DC 20528–0610, Telephone 703–235–5263. For additional information on the Appendix A meeting, please email CFATS@hq.dhs.gov. Individuals with access and functional needs wishing to attend the session and require accommodations should contact Sharmine Jones at Sharmine.Jones@hq.dhs.gov as soon as possible.

SUPPLEMENTARY INFORMATION:

Abbreviations and Terms Used in This Document

ASP Alternative Security Program
 CAS Chemical Abstract Service
 CFATS Chemical Facility Anti-Terrorism Standards
 CFR Code of Federal Regulations
 COI Chemicals of Interest
 CSAT Chemical Security Assessment Tool
 CVI Chemical-terrorism Vulnerability Information
 DHS or Department Department of Homeland Security
 FR Federal Register
 SSP Site Security Plan
 STQ Screening Threshold Quantity
 SVA Security Vulnerability Assessment

I. Background

Section 550 of the Department of Homeland Security Appropriations Act of 2007 (Pub. L. 109–295) authorized the Department to regulate the security of chemical facilities that, in the discretion of the Secretary, may present high levels of security risk. Under the Section 550 authority, on April 9, 2007, DHS issued the CFATS interim final rule, 6 CFR part 27. *See* 72 FR 17688. Additionally, in November 2007, the Department adopted as Appendix A to the CFATS rule, a final list of over 300 Chemicals of Interest (COI) that pose significant risks to human life or health if released, stolen or diverted, or sabotaged or contaminated. DHS also adopted some additional provisions that clarify how Appendix A is to be applied under CFATS. *See* 72 FR 65396. Publication of the Appendix A regulations brought the CFATS interim final rule into full effect.

On December 18, 2014, the President signed into law the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014, (“the Act”) (Pub. L. 113–254 (6 U.S.C. 621 *et seq.*)), which authorizes the CFATS program. The Act supersedes Section 550 of the Department of Homeland Security Appropriations Act of 2007, Public Law 109–295, as amended, under which the CFATS program was originally established in April 2007. The CFATS regulations, 6 CFR part 27, remain in effect. Under CFATS, any chemical facility (other than certain facilities expressly exempted by statute) that possesses any COI at or above the threshold amounts (applicable Screening Threshold Quantity (STQ) or minimum concentration) specified in Appendix A for that COI must complete and submit to DHS through the Chemical Security Assessment Tool (CSAT)¹ certain information (the “Top-Screen”).

II. Scope of Roundtable Discussion and Listening Session

DHS is interested in obtaining information and recommendations from the public on Appendix A. Comments and recommendations are welcomed on all aspects of CFATS Appendix A;

¹ CSAT is an information technology system primarily designed to collect facility information through specific applications for submitting Top-Screens, Security Vulnerability Assessments (SVAs), Site Security Plans (SSPs), and Alternative Security Programs (ASPs). *See* 6 CFR 27.105.

however, DHS is particularly interested in hearing about the following topics:

- The possible addition of chemicals to, and/or the deletion or modification of COI currently listed in Appendix A;
- The applicability and/or modification of any Screening Threshold Quantities (STQ) or minimum concentrations;
- Concentration and mixtures rules associated with Appendix A, which are described in 6 CFR 27.204;
- Isotopic variants to include comments on Chemical Abstract Service (CAS) Registry Numbers and nomenclature;
- The classification of COI within different security issues, to include the potential for re-designating certain chemicals now listed solely as release flammable so they are listed solely as toxic or as toxic and flammable; and
- Criteria for “counting rules” for screening threshold quantities to include clarification on how to determine if a COI is in transportation.

III. Written Comments

A. General

All interested persons, even those who are unable to attend the roundtable discussion and/or public listening session in-person, may submit written comments, data, or views on how Appendix A of the current CFATS regulations, 6 CFR part 27, might be improved. Please explain the reason for any comments and include other information or authority that supports such comments. Feedback that simply states that a stakeholder feels strongly that DHS should modify the Appendix A COI list will not enable the Department to adequately evaluate the commenter's concern, nor could DHS propose possible changes to address the commenter's feedback. Therefore the Department requests that commenters provide actionable data, including how the proposed change would impact the costs and benefits of CFATS, to allow the Department to fully consider the commenter's comment and recommendation.

Written comments may be submitted electronically or by mail, as explained previously in the **ADDRESSES** section of this Notice. To avoid duplication, please use only one of these methods to submit written comments. Written comments will not be accepted at this public meeting.

Except as provided below, all comments received, as well as pertinent background documents, will be posted without change to <http://www.regulations.gov>, including any personal information provided. All

submissions must include the agency name and docket number for this rulemaking. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

B. Handling of Confidential, Sensitive and Chemical-Terrorism Vulnerability Information

Interested parties are encouraged to submit comments in a manner that avoids discussion of trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI), or any other category of sensitive information that should not be disclosed to the general public. If it is not possible to avoid such discussion, however, please specifically identify any confidential or sensitive information contained in the comments with appropriate warning language (e.g., any CVI must be marked and handled in accordance with the requirements of 6 CFR 27.400(f)), and submit them by mail to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section.

DHS will not place any identifiable confidential or sensitive comments in the public docket; rather, DHS will handle them in accordance with applicable safeguards and restrictions on access. See e.g., 6 CFR 27.400. See also the DHS CVI Procedural Manual, “Safeguarding Information Designated as CVI,” September 2008, located on the DHS Web site at: www.dhs.gov/critical-infrastructure-chemical-security. DHS will hold any such comments in a separate file to which the public does not have access and place a note in the public docket that DHS has received such materials from the commenter. DHS will provide appropriate access to such comments upon request to individuals who meet the applicable legal requirements for access to such information.

IV. Roundtable Discussion and Listening Session

A. Purpose

The Department will hold a public roundtable discussion and listening session to solicit the public's views and recommendations on how the current Appendix A COI list might be improved.

B. Procedures and Participation

This meeting is open to the public. DHS will use sign-in sheets to voluntarily collect contact information from the attending public and to properly log oral comments received during the two sessions. Providing

contact information will be voluntary, and members of the public also may make anonymous oral comments. Seating may be limited, but session organizers will make every effort to accommodate all participants. Please note that members of the public who participate through the listen-only webinar may log in as a guest on the Homeland Security Information Network. This log in does not require your full name or a password. As previously stated, comments will not be accepted through the webinar. If you wish to submit a written comment please submit through the methods identified in the **ADDRESSES** section. The roundtable discussion is intended for technical experts, who have a scientific, security, regulatory or other background to discuss the proposed topics regarding Appendix A at an expert level. However, individuals who are not technical experts (or who do not meet the other criteria) may still attend and participate in the meeting. The listening session is intended to afford the public an opportunity to provide comments to the Department concerning CFATS and the Appendix A. For the listening session, comments are requested not to exceed four minutes at a time to enable all interested attendees an opportunity to provide comment. Should time permit, commenters who need additional time may be invited to complete their comments. The listening session may adjourn early if all commenters present have had the opportunity to speak prior to the scheduled conclusion of the session. Participants who speak will be asked to provide their name, title, company and stakeholder segment (i.e. chemical producers, chemical storage companies, agricultural supply companies, state and local regulators, chemical critical infrastructure owners and operators, etc.). Notes from the listening session will be posted at <http://www.regulations.gov>. The public roundtable discussion and listening session also may be recorded to support the note-taking effort.

DHS will place a transcript of the public meeting in the docket for this rulemaking.

In addressing these topics, DHS encourages interested parties to provide specific data that documents the costs, burdens, and benefits of the current regulatory approach. Commenters also might address how DHS can best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of Appendix A, and whether there are lower cost alternatives that would to allow the

Department to continue to achieve its security goals consistent with the law.

David M. Wulf,

*Director for Infrastructure Security
Compliance Division, Department of
Homeland Security.*

[FR Doc. 2015-26200 Filed 10-15-15; 8:45 am]

BILLING CODE 9110-9P-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Doc. No. AMS-FV-14-0069; FV-14-989-2 PR]

Raisins Produced From Grapes Grown in California; Proposed Amendments to Marketing Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites public comments on proposed amendments to Marketing Order No. 989, which regulates the handling of raisins produced from grapes grown in California. The Raisin Administrative Committee (Committee), which is responsible for the local administration of the order and is comprised of producers and handlers of raisins operating within the production area, recommended the amendments that would authorize the Committee to borrow from a commercial lending institution and authorize the establishment of a monetary reserve equal to up to one year's budgeted expenses. Allowing the Committee to utilize these customary business practices would help to improve administration of the order.

DATES: Comments must be received by December 15, 2015.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Fax: (202) 720-8938; or Internet: <http://www.regulations.gov>. Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>. All comments submitted in response to this proposal will be included in the record

and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT:

Geronimo Quinones, Marketing Specialist, or Michelle P. Sharrow, Rulemaking Branch Chief, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: geronimo.quinones@ams.usda.gov or michelle.sharrow@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Jeffrey Smutny, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: Jeffrey.Smutny@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Order No. 989, as amended (7 CFR part 989), regulating the handling of raisins produced from grapes grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than

20 days after the date of the entry of the ruling.

Section 1504 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) (Pub. L. 110-246) amended section 18c(17) of the Act, which in turn required the addition of supplemental rules of practice to 7 CFR part 900 (73 FR 49307; August 21, 2008). The additional supplemental rules of practice authorize the use of informal rulemaking (5 U.S.C. 553) to amend Federal fruit, vegetable, and nut marketing agreements and orders. USDA may use informal rulemaking to amend marketing orders based on the nature and complexity of the proposed amendments, the potential regulatory and economic impacts on affected entities, and any other relevant matters.

AMS has considered these factors and has determined that the amendment proposals are not unduly complex and the nature of the proposed amendments is appropriate for utilizing the informal rulemaking process to amend the order. A discussion of the potential regulatory and economic impacts on affected entities is discussed later in the "Initial Regulatory Flexibility Analysis" section of this rule.

The proposed amendments were unanimously recommended by the Committee following deliberations at a public meeting held on October 2, 2014. Currently, the order does not allow the Committee to borrow funds from a commercial lending institution or retain unspent handler assessments past the close of a fiscal year. Allowing the Committee to utilize these customary business practices would help to improve administration of the order by providing it with the means for ensuring continuity of operations when its cash flow needs are greater than available handler assessment income.

Proposal #1—Borrowing From a Commercial Lending Institution

Section 989.80 of the order, Assessments, authorizes the Committee to collect assessments from handlers to administer the program.

This proposal would provide the Committee with authority to borrow from a commercial lending institution during times of cash shortages. Since inception of the marketing order, the Committee sometimes has used the order's volume regulation provisions to pool a portion of the annual raisin crop to assure orderly marketing. These pooled raisins, designated by the Committee as reserve raisins, were sold and released to handlers throughout the crop year. In managing the pooled raisins for the best return to growers, the Committee pooled the cash received

from the handlers until equity payments were distributed to the growers. The Committee borrowed funds (with interest) from this reserve raisin pool during times of assessment shortages to temporarily cover expenses, generally during the early part of the new crop year.

Volume regulation has not been in effect under the marketing order since 2010, and the Committee has been returning equity payments to the growers who contributed raisins to the 2009 reserve raisin pool. Therefore, funds from the reserve raisin pool are no longer available for the Committee to use during times of cash shortages. The Committee's proposed amendment to the order would allow it to borrow from a commercial lending institution when no other funding is available. This would assist the Committee in bridging finances from the end of one fiscal year through the first quarter of the new fiscal year before assessments on the new crop are received.

Additionally, the Committee has received grants from the Foreign Agricultural Service's (FAS) Market Access Program (MAP) since 1995 to conduct market expansion and development activities in various international markets. Under MAP, participants must first use their own resources for activities and request reimbursement from FAS. Sometimes there is a time-lag between submission of reimbursement requests and receipt of payments, which causes budgeting issues. Having authority to borrow from a commercial lending institution would help to ensure continuity of operations when this occurs.

Therefore, for the reasons stated above, it is proposed that § 989.80, Assessments, be amended by adding a sentence in paragraph (c) that would provide the Committee with authority to borrow from a commercial lending institution when no other funding is available.

Proposal #2—Establish a Monetary Reserve Fund Equal to One Year's Budgeted Expenses

Section 989.81 of the order, Accounting, authorizes the Committee to credit or refund unexpended assessment funds from the crop year back to the handlers from whom it was collected. Currently, the order doesn't allow the Committee to retain handler assessments from prior crop years.

This proposal would allow the Committee to establish a monetary reserve equal to one year's operational expenses as averaged over the past six years. Reserve funds could be used for specific administrative and overhead

expenses such as staff wages, salaries and related benefits, office rent, utilities, postage, insurance, legal expenses, and audit costs; to cover deficits incurred during any period when assessment income is less than expenses; to defray expenses incurred during any period when any or all provisions of the order are suspended; liquidation of the order; and other expenses recommended by the Committee and approved by the Secretary. Reserve funds could not be used for promotional expenses during any crop year prior to the time that assessment income is sufficient to cover such expenses.

As previously stated in Proposal #1, the Committee borrowed cash from the reserve raisin pool and repaid it with interest when handler assessment cash shortages occurred in the past. This practice helped the Committee to bridge finances from one fiscal crop year to the next until assessment income for the new crop year was received. This option is no longer available.

For the reasons stated above, it is proposed that § 989.81, Accounting, be amended to allow the Committee to retain excess assessment funds for the purpose of establishing a monetary reserve equal to one year's budgeted expenses as averaged over the past six years. Such excess funds could only be used for specific administrative and operational expenses.

Initial Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 3,000 producers of California raisins and approximately 28 handlers subject to regulation under the marketing order. The Small Business Administration defines small agricultural producers as those having annual receipts of less than \$750,000 and defines small agricultural service firms as those whose annual receipts are less than \$7,000,000 (13 CFR 121.201).

Based upon information provided by the Committee, it may be concluded that a majority of producers and approximately 18 handlers of California raisins may be classified as small entities.

The proposed rule would authorize the Committee to borrow from commercial lending institutions and to establish a monetary reserve fund equal to one year's budgeted expenses. This would help to ensure proper management and funding of the program.

The Committee reviewed and identified a yearly budget that would be necessary to continue program operations in the absence of a reserve pool. Based on this budget, the Committee believes a monetary reserve of approximately \$2 million would be sufficient to continue operations. The anticipated \$2 million to be accumulated in a monetary reserve would not be accrued in one crop year. It would be spread over several years, depending on expenses, assessment revenue, and excess handler assessments accrued in each crop year. For example: If excess annual handler assessments amount to \$400,000, it would take five years to accrue \$2 million. Currently, the average excess handler assessments paid yearly over the last six years has been \$861,622. During the time in which the monetary reserve fund would be accumulated, the Committee would seek funding from a commercial lending institution as previously explained in Proposal #1.

While this action would result in a temporary increase in handler costs, these costs would be uniform on all handlers and proportional to the size of their businesses. However, these costs are expected to be offset by the benefits derived from operation of the order. Additionally, these costs would help to ensure that the Committee has sufficient funds to meet its financial obligations. Such stability is expected to allow the Committee to conduct programs that would benefit all entities, regardless of size. California raisin producers should see an improved business environment and a more sustainable business model because of the improved business efficiency.

Alternatives were considered to these proposals, including making no changes at this time. However, the Committee believes it would be beneficial to have the means and funds necessary to effectively administer the program.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information

collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581-0178, "Vegetable and Specialty Crops." No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California raisin handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Committee's meeting was widely publicized throughout the California raisin production area. All interested persons were invited to attend the meeting and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the October 2, 2014, meeting was public, and all entities, both large and small, were encouraged to express their views on these proposals. Finally, interested persons are invited to submit comments on the proposed amendments to the order, including comments on the regulatory and informational impacts of this action on small businesses.

Following analysis of any comments received on the amendments proposed in this rule, AMS will evaluate all available information and determine whether to proceed. If appropriate, a proposed rule and referendum order would be issued, and producers would be provided the opportunity to vote for or against the proposed amendments. Information about the referendum, including dates and voter eligibility requirements, would be published in a future issue of the **Federal Register**. A final rule would then be issued to effectuate any amendments favored by producers participating in the referendum.

AMS is committed to complying with the E-Government Act 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.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action. A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide>. Any questions about the compliance guide should be sent to Jeffrey Smutny

at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

General Findings

The findings hereinafter set forth are supplementary to the findings and determinations which were previously made in connection with the issuance of the marketing order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

1. The marketing order as hereby proposed to be amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. The marketing order as hereby proposed to be amended regulates the handling of raisins produced by grapes grown in California and is applicable only to persons in the respective classes of commercial and industrial activity specified in the marketing order;

3. The marketing order as hereby proposed to be amended is limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

4. The marketing order as hereby proposed to be amended prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of raisins produced or packed in the production area; and

5. All handling of raisins produced or packed in the production area as defined in the marketing order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

A 60-day comment period is provided to allow interested persons to respond to these proposals. Any comments received on the amendments proposed in this rule will be analyzed, and if AMS determines to proceed based on all the information presented, a producer referendum would be conducted to determine producer support for the proposed amendments. If appropriate, a final rule would then be issued to effectuate the amendments favored by producers participating in the referendum.

List of Subjects in 7 CFR Part 989

Raisins, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 989 is proposed to be amended as follows:

PART 989—RAISINS PRODUCED BY GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 989 continues to read as follows:

Authority: 7 U.S.C. 601-674.

■ 2. Revise paragraph (c) of § 989.80 to read as follows:

§ 989.80 Assessments.

* * * * *

(c) During any crop year or any portion of a crop year for which volume percentages are not effective for a varietal type, all standard raisins of that varietal type acquired by handlers during such period shall be free tonnage for purposes of levying assessments pursuant to this section. The Secretary shall fix the rate of assessment to be paid by all handlers on the basis of a specified rate per ton. At any time during or after a crop year, the Secretary may increase the rate of assessment to obtain sufficient funds to cover any later finding by the Secretary relative to the expenses of the committee. Each handler shall pay such additional assessment to the committee upon demand. In order to provide funds to carry out the functions of the committee, the committee may accept advance payments from any handler to be credited toward such assessments as may be levied pursuant to this section against such handler during the crop year. In the event cash flow needs of the committee are above cash available generated by handler assessments, the committee may borrow from a commercial lending institution. The payment of assessments for the maintenance and functioning of the committee, and for such purposes as the Secretary may pursuant to this subpart determine to be appropriate, may be required under this part throughout the period it is in effect, irrespective of whether particular provisions thereof are suspended or become inoperative.

* * * * *

■ 3. Revise paragraph (a) of § 989.81 to read as follows:

§ 989.81 Accounting.

(a) If, at the end of the crop year, the assessments collected are in excess of expenses incurred, such excess shall be accounted for in accordance with one of the following:

(1) If such excess is not retained in a reserve, as provided in paragraph (a)(2) of this section, it shall be refunded proportionately to the persons from whom collected in accordance with § 989.80; *Provided*, That any sum paid by a person in excess of his or her pro rata share of expenses during any crop year may be applied by the committee at the end of such crop year as credit for such person, toward the committee's administrative operations for the following crop year; *Provided further*, That the committee may credit the excess to any outstanding obligations due the committee from such person.

(2) The committee may carry over such excess funds into subsequent crop years as a reserve; *Provided*, That funds already in the reserve do not exceed one crop year's budgeted expenses as averaged over the past six years. In the event that funds exceed one crop year's expenses, funds in excess of one crop year's budgeted expenses shall be distributed in accordance with paragraph (1) above. Such funds may be used:

(i) To defray essential administrative expenses (*i.e.*, staff wages/salaries and related benefits, office rent, utilities, postage, insurance, legal expenses, audit costs, consulting, Web site operation and maintenance, office supplies, repairs and maintenance, equipment leases, domestic staff travel and committee mileage reimbursement, international committee travel, international staff travel, bank charges, computer software and programming, costs of compliance activities, and other similar essential administrative expenses) exclusive of promotional expenses during any crop year, prior to the time assessment income is sufficient to cover such expenses;

(ii) To cover deficits incurred during any period when assessment income is less than expenses;

(iii) To defray expenses incurred during any period when any or all provisions of this part are suspended;

(iv) To meet any other such expenses recommended by the committee and approved by the Secretary; and

(v) To cover the necessary expenses of liquidation in the event of termination of this part. Upon such termination, any funds not required to defray the necessary expenses of liquidation shall be disposed of in such manner as the Secretary may determine to be appropriate; *Provided*, That to the extent practicable, such funds shall be returned pro rata to the persons from whom such funds were collected.

Dated: October 13, 2015.

Rex Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015-26378 Filed 10-15-15; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2015-1139; Airspace Docket No. 15-AWP-4]

Proposed Establishment of Class E Airspace; Los Angeles, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E surface area airspace designated as an extension to the Class D airspace at Whiteman Airport, Los Angeles, CA. After reviewing the airspace, the FAA found it necessary to establish Class E surface area for the safety and management of Instrument Flight Rules (IFR) operations for at the airport.

DATES: Comments must be received on or before November 30, 2015.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366-9826. You must identify FAA Docket No. FAA-2015-1139; Airspace Docket No. 15-AWP-4, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202-267-8783. The Order is also available

for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT:

Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4500.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace at Whiteman Airport, Los Angeles, CA.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2015-1139; Airspace Docket No. 15-AWP-4." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E surface area airspace designated as an extension to the Class D airspace at Whiteman Airport, Los Angeles, CA. The Class E surface area airspace would extend from the 3-mile radius of Whiteman Airport to 6.6 miles northwest of the airport for the safety and management of IFR operations.

Class E airspace designations are published in paragraph 6004, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area

* * * * *

AWP CA E4 Whiteman, CA [New]

Los Angeles, Whiteman Airport, CA
(Lat. 34°15'34" N., long. 118°24'48" W.)
That airspace extending upward from the surface within 1.1 miles each side of the 304°

bearing from the Whiteman Airport, extending from the 3-mile radius of Whiteman Airport to 6.6 miles northwest of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in Seattle, Washington, on October 6, 2015.

Mindy Wright,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015-26097 Filed 10-15-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 203

[Docket No. FR-5742-N-02]

RIN 2502-AJ23

Federal Housing Administration (FHA): Single Family Mortgage Insurance Maximum Time Period for Filing Insurance Claims, Curtailment of Interest and Disallowance of Operating Expenses Incurred Beyond Certain Established Timeframes; Partial Withdrawal

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Partial withdrawal of proposed rule.

SUMMARY: This document withdraws part of a proposed rule, published in the *Federal Register* on July 6, 2015, that proposed to establish a maximum time period within which an FHA-approved mortgagee must file a claim with FHA for insurance benefits, and to revise HUD's policies concerning the curtailment of interest and the disallowance of certain expenses incurred by a mortgagee as a result of the mortgagee's failure to timely initiate foreclosure or timely take such other action that is a prerequisite to submission of a claim for insurance. This withdrawal covers only the portion of the proposed rule that would have established the maximum time period within which an FHA-approved mortgagee must file a claim with FHA for insurance benefits.

DATES: As of October 16, 2015, HUD withdraws the proposed additions of §§ 203.317a and 203.372, and proposed revision to § 203.318, published Monday, July 6, 2015 (80 FR 38410).

FOR FURTHER INFORMATION CONTACT: Ivery Himes, Director, Office of Single

Family Asset Management, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 9172, Washington, DC 20410; telephone number 202-708-1672 (this is not a toll-free number). Persons with hearing or speech impairments may access this number by calling the Federal Relay Service at 800-877-8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On July 6, 2015, HUD published in the **Federal Register** a proposed rule that would have added § 203.372, establishing a maximum time period for filing a claim for insurance benefits, and § 203.317a, providing that the contract of insurance would be terminated if a mortgagee failed to file a claim within the maximum time period specified in § 203.372, to 24 CFR part 203. The proposed rule would have also revised § 203.318 to refer to termination of the insurance contract under new § 203.317a. Additionally, the proposed rule would amend § 203.402, and revise the title of § 203.474, related to proposals concerning the curtailment of interest and the disallowance of certain expenses incurred by a mortgagee as a result of the mortgagee's failure to timely initiate foreclosure or timely take such other action that is a prerequisite to submission of a claim for insurance.

In response to public comments expressing concern over the implementation of the proposed provisions regarding the maximum time period within which an FHA-approved mortgagee must file a claim with FHA for insurance benefits, HUD is withdrawing the proposed additions of §§ 203.317a and 203.372, and proposed revision to § 203.318. HUD will publish in the **Federal Register** any revised maximum time period for claim filing provisions in a proposed rule and solicit public comment on it.

List of Subjects in 24 CFR Part 203

Hawaiian Natives, Home improvement, Indians-lands, Loan programs-housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

Partial Withdrawal of Proposed Rule. For the reasons stated in the preamble and under the authority of 42 U.S.C. 3535(d), HUD withdraws the proposed additions of §§ 203.317a and 203.372, and proposed revision to § 203.318, in 24 CFR part 203.

Dated: October 7, 2015.

Edward L. Golding,

Principal Deputy Assistant Secretary for Housing.

[FR Doc. 2015-26379 Filed 10-15-15; 8:45 am]

BILLING CODE 4210-67-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2015-0240 FRL-9935-55-Region 9]

Approval of Implementation Plans; Arizona, Phoenix-Mesa; 2008 Ozone Standard Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Arizona State Implementation Plan (SIP) concerning the emission inventory, emission statements, reasonably available control technology corrections and the vehicle inspection and maintenance requirements for the Phoenix-Mesa 2008 eight-Hour Ozone National Ambient Air Quality Standard (NAAQS) Marginal nonattainment area. We are approving these revisions under the Clean Air Act. **DATES:** Any comments on this proposal must arrive by November 16, 2015.

ADDRESSES: Submit comments, identified by docket number EPA-R09-OAR-2015-0240, by one of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the on-line instructions.
2. *Email:* levin.nancy@epa.gov.
3. *Mail or deliver:* Nancy Levin (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Instructions: Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit <http://www.epa.gov/dockets/comments.html> for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. For additional

submission methods, the full EPA public comment policy, and general guidance on making effective comments, please visit <http://www.epa.gov/dockets/comments.html>.

Docket: Generally, documents in the docket for this action are available electronically at www.regulations.gov or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105-3901. While all documents in the docket are listed at www.regulations.gov, some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, (415) 972-3848, levin.nancy@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA. This proposal addresses revisions to the Arizona SIP concerning the emission inventory, emission statements, reasonably available control technology corrections and the vehicle inspection and maintenance requirements for the Phoenix-Mesa 2008 eight-Hour Ozone NAAQS Marginal nonattainment area. In the Rules and Regulations section of this **Federal Register**, we are approving these revisions in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 25, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015-26024 Filed 10-15-15; 8:45 am]

BILLING CODE 6560-50-P

**FEDERAL COMMUNICATIONS
COMMISSION****47 CFR Part 54**

[GN Docket No. 12–354; Report No. 3029]

**Petitions for Reconsideration of Action
in Rulemaking Proceeding; Correction****AGENCY:** Federal Communications
Commission.**ACTION:** Petitions for reconsideration;
correction.**SUMMARY:** The Federal Communications
Commission published in the **Federal
Register** of October 2, 2015, a document
concerning Petitions for

Reconsideration in the Commission's
Rulemaking proceeding. This document
corrects the **DATES** section and replaces
"October 13, 2015" with "October 29,
2015" as the correct due date for replies
to oppositions.

DATES: Replies to opposition are due on
October 29, 2015.**FOR FURTHER INFORMATION CONTACT:** Paul
Powell, 202–418–1613; Email:
paul.powell@fcc.gov.**SUPPLEMENTARY INFORMATION:** The FCC
published a document in the **Federal
Register** at 80 FR 59705, October 2,
2015, inadvertently setting October 13,
2015 as the due date for replies to
oppositions to Petitions for

Reconsideration. This correction
replaces the incorrect date with the
correct date.

In proposed rule 2015–25001
published at 80 FR 59705, October 2,
2015, make the following correction. On
page 59705, in the first column, in the
DATES section state that the "replies to
the opposition are due on "October 29,
2015," in lieu of "October 13, 2015."

Federal Communications Commission

Marlene H. Dortch,*Secretary.*

[FR Doc. 2015–26305 Filed 10–15–15; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 80, No. 200

Friday, October 16, 2015

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.

AFRICAN DEVELOPMENT FOUNDATION

Public Quarterly Meeting of the Board of Directors

AGENCY: United States African Development Foundation.

ACTION: Notice of meeting.

SUMMARY: The U.S. African Development Foundation (USADF) will hold its quarterly meeting of the Board of Directors to discuss the agency's programs and administration.

DATES: The meeting date is Tuesday, October 27, 2015, 9:00 a.m. to 11:30 a.m.

ADDRESSES: The meeting location is 1400 I Street Northwest, Suite #1000 (Main Conference Room), Washington, DC 2005-2246.

FOR FURTHER INFORMATION CONTACT: Julia Lingham, 202-233-8811.

Authority: Pub. L. 96-533 (22 U.S.C. § 290h).

Dated: October 13, 2015.

Doris Mason Martin,
General Counsel.

[FR Doc. 2015-26387 Filed 10-15-15; 8:45 am]

BILLING CODE 6117-01-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document No. AMS-ST-15-0060]

Plant Variety Protection Board; Open Meeting

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Agricultural Marketing Service (AMS) is announcing a meeting of the Plant Variety Protection Board (Board). The meeting is being held to discuss a variety of topics including, but not

limited to, work and outreach plans, subcommittee activities, and proposals for procedure changes. The meeting is open to the public. This notice sets forth the schedule and location for the meeting.

DATES: Monday, December 7, 2015, from 1:00 p.m. to 5:00 p.m. and Tuesday, December 8, 2015, from 8:00 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be held at the Hyatt Regency Chicago Hotel at the Ogden Room, at 151 East Wacker Drive, Chicago, IL 60601.

FOR FURTHER INFORMATION CONTACT:

Maria Pratt, Program Analyst, U.S. Department of Agriculture (USDA), AMS, Science and Technology Programs, 1400 Independence Avenue SW., Washington, DC 20250. Telephone number (202) 720-1104, fax (202) 260-8976, or email: maria.pratt@ams.usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of section 10(a) of the FACA (5 U.S.C. Appendix 2), this notice informs the public that the Plant Variety Protection Office (PVPO) is having a Board meeting within the 15 day requirement of the FACA. The Plant Variety Protection Act (PVPA) (7 U.S.C. 2321 *et seq.*) provides legal protection in the form of intellectual property rights to developers of new varieties of plants, which are reproduced sexually by seed or are tuber-propagated. A certificate of Plant Variety Protection (PVP) is awarded to an owner of a crop variety after an examination shows that it is new, distinct from other varieties, genetically uniform and stable through successive generations. The term of protection is 20 years for most crops and 25 years for trees, shrubs, and vines. The PVPA also provides for a statutory Board (7 U.S.C. 2327). The PVPA Board is composed of 14 individuals who are experts in various areas of development and represent the private or seed industry sector, academia and government. The duties of the Board are to: (1) Advise the Secretary concerning the adoption of rules and regulations to facilitate the proper administration of the FACA; (2) provide advisory counsel to the Secretary on appeals concerning decisions on applications by the PVP office and on requests for emergency public-interest compulsory licenses; and (3) advise the Secretary on any other matters under the Regulations and Rules

of Practice and on all questions under Section 44 of the FACA, "Public Interest in Wide Usage" (7 U.S.C. 2404).

The purpose of the meeting will be to discuss the PVPO 2015 achievements, the electronic application system, reports of the outreach and molecular techniques subcommittees, PVP cooperation with other countries, and PVPO 2016 business plan.

Agenda Items: The agenda will include, welcome and introductions, discussions on program activities that encourage the development of new plant varieties and also address appeals to the Secretary. There will be presentations on 2015 accomplishments, the electronic PVP application system, PVP outreach activities, the use of molecular markers for PVP applications, PVP cooperation with other countries, and the 2016 business plan. The meeting will be open to the public. Those wishing to participate are encouraged to pre-register by November 30, 2015 by contacting Maria Pratt, Program Analyst; Telephone: (202) 720-1104; Email: maria.pratt@ams.usda.gov.

Meeting Accommodation: The meeting hotel is ADA compliant, and the USDA provides reasonable accommodations to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in this public meeting, please notify Maria Pratt at: Email: maria.pratt@ams.usda.gov or (202) 720-1104. Determinations for reasonable accommodation will be made on a case-by-case basis. Minutes of the meeting will be available for public review at the Internet Web site <http://www.ams.usda.gov/PVPO>.

Dated: October 13, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015-26377 Filed 10-15-15; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Current Population Survey (CPS) Fertility Supplement

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, written comments must be submitted on or before December 15, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Karen Woods, U.S. Census Bureau, 7H110F, Washington, DC 20233–8400 at (301) 763–3806.

SUPPLEMENTARY INFORMATION**I. Abstract**

The U.S. Census Bureau plans to request clearance for the collection of data concerning the Fertility Supplement to be conducted in conjunction with the June 2016 CPS. The Census Bureau sponsors the supplement questions, which were previously collected in June 2014, and have been asked periodically since 1971. Title 13 U.S.C. Sections 141 and 182 authorize the collection of this information on individuals and households. This year, the 2016 Fertility Supplement will include questions on marital status and cohabitation of women at the time of their first birth.

This survey provides information used mainly by government and private analysts to project future population growth, to analyze child spacing, and to aid policymakers in their decisions affected by changes in family size and composition. Past studies have discovered noticeable changes in the patterns of fertility rates and the timing of the first birth. Potential needs for government assistance, such as aid to families with dependent children, child care, and maternal health care for single parent households, can be estimated using CPS characteristics matched with fertility data.

II. Method of Collection

The fertility information will be collected by both personal visit and telephone interviews in conjunction with the regular June CPS interviewing. All interviews are conducted using computer-assisted interviewing.

III. Data

OMB Control Number: 0607–0610.

Form Number: There are no forms. We conduct all interviewing on computers.

Type of Review: Regular submission.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 30,000.

Estimated Time per Response: 1 minute.

Estimated Total Annual Burden Hours: 500.

Estimated Total Annual Cost: There are no costs to the respondents other than their time to answer the CPS questions.

Respondents Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Sections 141, 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 9, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–26308 Filed 10–15–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE**International Trade Administration****Healthcare Technology & Hospital Information Services Trade Mission to the Kingdom of Saudi Arabia and Kuwait**

April 23–28, 2016.

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Department of Commerce, International Trade Administration (ITA), with support from the U.S. Chamber of Commerce and organizers of the Saudi-American Healthcare Forum (SAHF) is organizing a Healthcare Technology & Hospital Information Services Trade Mission to the Kingdom of Saudi Arabia and Kuwait from April 23–28, 2016. The purpose of the mission is to introduce U.S. firms to the rapidly expanding healthcare sectors in these two countries and to assist U.S. companies in pursuing opportunities in this sector.

The mission is designed for U.S. companies and international hospital groups providing hospital operation and management services, hospital information systems, and eHealth solutions. The mission also will assist U.S. companies already doing business in Saudi Arabia and Kuwait to expand their footprint. Target sectors holding high potential for U.S. companies include:

- Hospital operation and management,
- healthcare training and staffing services,
- healthcare education, and
- health information systems and informatics (e.g., electronic health records).

The mission is timed to take place during the Saudi-American Healthcare Forum (SAHF) on April 25–27, 2016. The SAHF is an exclusive event dedicated to building new relationships, fostering existing partnerships, and exchanging best practices between the United States and the Middle East. The 2015 forum attracted over 1,000 attendees intent on promoting healthcare diplomacy through bilateral and international research, technology development, and education and training. Approximately 50 U.S. companies and organizations attended the event. Additional information about the SAHF can be found here: <http://sahf15.com/>.

Supported by American industry participants and the U.S. Embassy, the

2016 SAHF will showcase the ongoing health-related cooperation between the U.S. Government and Saudi healthcare counterparts. The U.S. trade mission participants will be highlighted at the SAHF through speaking roles designed to elevate their companies' visibility as thought leaders in the field of healthcare innovation. Trade mission participants also will have free access to all seminars offered at the SAHF, if they wish to participate. Additionally, through customized meetings organized by the U.S. Commercial Service, trade mission participants will gain access to top level Saudi health decision makers to gain

exposure they would not otherwise be able to achieve on their own.

The mission will help participating U.S. firms and associations/organizations gain market insights, make industry and government contacts, solidify business strategies and advance specific projects with the goal of increasing U.S. healthcare services exports. The trade mission will start in Riyadh, Saudi Arabia, where participants will receive market briefings from U.S. Commercial Service and industry experts, hold one-on-one business meetings, meet with Saudi government officials and organizations, and participate in networking events. Delegates will be invited to participate

in the SAHF. Following the SAHF, trade mission participants will travel to Jeddah, Saudi Arabia and then to Kuwait, where they will have additional opportunities to meet with key contacts and decision makers. Participating firms may also wish to remain in Riyadh, or if the firm decides to send two participants on the mission, one representative can remain in Riyadh, rather than continue to Jeddah, to participate in SAHF seminars. Participating in an official U.S. industry delegation, rather than traveling on their own, will enhance the companies' abilities to identify opportunities in Saudi Arabia and Kuwait.

SCHEDULE

Saturday—April 23, Riyadh, Saudi Arabia	<ul style="list-style-type: none"> • Arrive Riyadh and hotel check-in • Welcome reception/ice breaker
Sunday—April 24, Riyadh, Saudi Arabia	<ul style="list-style-type: none"> • Welcome and overview of Trade Mission (TM) • Market briefings from the U.S. Commercial Service and industry experts • One-on-one business meetings • Networking reception in Riyadh
Monday—April 25, Riyadh, Saudi Arabia	<ul style="list-style-type: none"> • Government meetings • Saudi-American Healthcare Forum (SAHF) speaking engagements for trade mission participants • SAHF opening ceremony & gala dinner
Tuesday—April 26, Riyadh & Jeddah	<ul style="list-style-type: none"> • SAHF speaking engagements/TM split • Some TM representatives depart for Jeddah (PM) • Networking reception in Jeddah
Wednesday—April 27, Jeddah + Kuwait	<ul style="list-style-type: none"> • One-on-one business meetings Jeddah (AM) • Depart for Kuwait City, Kuwait (PM) • Networking reception in Kuwait
Thursday—April 28, Kuwait City, Kuwait	<ul style="list-style-type: none"> • Welcome and breakfast briefings • Government meetings • One-on-one business meetings • Mission ends

Web site: Please visit our official mission Web site for more information: <https://www.export.gov/trademiissions/saudikuwaitthehealthcare2016>.

Participation Requirements

All parties interested in participating in the trade mission must complete and submit an application package for consideration by the U.S. Department of Commerce. All applicants will be evaluated on their ability to meet certain conditions and best satisfy the selection criteria as Outlined below and will be notified whether they are chosen to participate in the mission. A minimum of 12 and maximum of 15 companies and/or trade associations/organizations will be selected from the applicant pool to participate in the trade mission.

Fees and Expenses

After an applicant has been selected to participate in the mission, a payment to the U.S. Department of Commerce in the form of a participation fee is required. Upon notification of acceptance to participate, those selected have five (5) business days to submit payment or the acceptance may be revoked.

The participation fee for the trade mission to Saudi Arabia and Kuwait is \$3,740 for small or medium-sized enterprises (SME) and \$4,470 for large companies. The fee for each additional representative (large firm or SME or trade association/organization) is \$750.

Exclusions

The mission fee does not include any personal travel expenses such as

lodging, most meals, local ground transportation (except for transportation to and from meetings, airport transfers during the mission) and air transportation. Participants will, however, be able to take advantage of U.S. Government per diem rates for hotel rooms. Business or entry visas may be required for participation in the mission. Applying for and obtaining such visas will be the responsibility of the mission participant. Government fees and processing expenses to obtain such visas are not included in the participation fee. However, the U.S. Department of Commerce will provide instructions to each participant on the procedures required to obtain necessary business visas.

Conditions for Participation

Applicants must submit a completed and signed mission application and supplemental application materials, including information on their products and/or services, primary market objectives, and goals for participation by February 12, 2016, but applications will be reviewed on a rolling basis beginning October 15, 2015 (see timeframe below). If the U.S. Department of Commerce receives an incomplete application, the Department may either: request additional information/clarification, take the lack of information into account when evaluating the application, or reject the application.

Each applicant must also certify that the products and services it seeks to export through the mission are either produced in the United States, or, if not, are marketed under the name of a U.S. company and have at least fifty-one percent U.S. content by value. In the case of a trade association or organization, the applicant must certify that, for each firm or service provider to be represented by the association/organization, the products and/or services the represented firm or service provider seeks to export are either produced in the United States or, if not, marketed under the name of a U.S. company and have at least fifty-one percent U.S. content.

In addition, each applicant must:

- Certify that the products and services that it wishes to market through the mission would be in compliance with U.S. export controls and regulations;
- Certify that it has identified any matter pending before any bureau or office in the U.S. Department of Commerce;
- Certify that it has identified any pending litigation (including any administrative proceedings) to which it is a party that involves the U.S. Department of Commerce;
- Sign and submit an agreement that it and its affiliates (1) have not and will not engage in the bribery of foreign officials in connection with a company's/participant's involvement in this mission, and (2) maintain and enforce a policy that prohibits the bribery of foreign officials; and
- Certify that it meets the minimum requirements as stated in this announcement. In the case of a trade association/organization, the applicant must certify that each firm or service provider to be represented by the association/organization can make the above certifications.

Selection Criteria for Participation

Targeted mission participants are U.S. manufacturers, services providers, and trade associations/organizations providing or promoting healthcare products/services that have an interest in entering or expanding their business in the Saudi and Kuwaiti markets. The following criteria will be evaluated in selecting participants:

- Suitability of a firm's or trade association's products or services to these markets;
- Firm's or trade association/organization's potential for business in the markets, including likelihood of exports resulting from the mission; and
- Consistency of the firm's or trade association/organization goals and objectives with the stated scope of the mission.

Additional factors, such as diversity of company size, type, location, and demographics, may also be considered during the review process. Referrals from political organizations and any documents, including the application, containing references to partisan political activities (including political contributions) will be removed from an applicant's submission and not considered during the selection process.

Timeline for Recruitment and Applications

Mission recruitment will be conducted in an open and public manner, including publication in the **Federal Register**, posting on the U.S. Commerce Department trade mission calendar (<http://www.export.gov/trademissions/>) and other Internet Web sites, press releases to general and trade media, direct mail, broadcast fax, notices by industry trade associations and other multiplier groups, and publicity at industry meetings, symposia, conferences, and trade shows. Recruitment for the mission will begin immediately and conclude no later than February 12, 2016. The U.S. Department of Commerce will review applications and make selection decisions on a rolling basis beginning October 15, 2015 until the maximum of 15 participants is selected. Applications received after February 12, 2016, will be considered only if space and scheduling constraints permit.

FOR FURTHER INFORMATION CONTACT: LeeAnne Haworth, U.S. Department of Commerce, Pittsburgh, PA, Tel: 412-644-2816, Email: leeanne.haworth@trade.gov.

Frank Spector,
Trade Missions Program.

[FR Doc. 2015-26008 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-929]

Small Diameter Graphite Electrodes From the People's Republic of China: Final Rescission of Antidumping Duty New Shipper Review; 2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 28, 2015, the Department of Commerce (the Department) published its *Preliminary Rescission* of the new shipper review of the antidumping duty order on small diameter graphite electrodes from the People's Republic of China (PRC) for the period of review (POR) of February 1, 2014, through August 31, 2014, for Xuzhou Jianglong Carbon Products Co., Ltd. (Jianglong).¹ For these final results, we continue to find that Jianglong's request does not satisfy the regulatory requirements for a new shipper review. Accordingly, we are rescinding the new shipper review for Jianglong.

DATES: *Effective date:* October 16, 2015.

FOR FURTHER INFORMATION CONTACT: Hermes Pinilla or Minoo Hatten, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-3477 or (202) 482-1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

In the *Preliminary Rescission*, the Department found that Jianglong is affiliated with Shanghai Carbon International Trade Co., Ltd. (Shanghai Carbon), which, as part of the PRC-wide Entity in the 2012-2013 administrative review, had shipments of subject merchandise to the United States. While conceding its affiliation with Shanghai Carbon, Jianglong did not certify its first U.S. entry or shipment and U.S. sale, as required under 19 CFR 351.214(b)(2)(iv)(A) and (C), respectively. Jianglong also did not request a new shipper review within one year of its first U.S. entry or shipment, as required by 19 CFR 351.214(c).

We received case and rebuttal briefs with respect to the *Preliminary Rescission* and, at the request of

¹ See *Small Diameter Graphite Electrodes from the People's Republic of China: Preliminary Rescission of Antidumping Duty New Shipper Review; 2014*, 80 FR 30438 (May 28, 2015) (*Preliminary Rescission*).

interested parties, held a hearing on August 5, 2015. We extended the due date for the final results of the review to October 5, 2015.² We conducted this new shipper review in accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214.

Scope of the Order

The merchandise covered by the order includes all small diameter graphite electrodes of any length, whether or not finished, of a kind used in furnaces, with a nominal or actual diameter of 400 millimeters (16 inches) or less, and whether or not attached to a graphite pin joining system or any other type of joining system or hardware. The subject merchandise is currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 8545.11.0010³ and 3801.10. The HTSUS numbers are provided for convenience and customs purposes, but the written description of the scope is dispositive. A full description of the scope of the order is contained in the Issues and Decision Memorandum.⁴

Final Rescission of Jianglong

As we explain in the Issues and Decision Memorandum, we continue to find that, because Jianglong is affiliated with an entity that had prior shipments of subject merchandise for consumption to the United States, and did not request a new shipper review within one year of those shipments, it is ineligible for a new shipper review. First, Jianglong did not certify its first U.S. entry or shipment and U.S. sale, as required under 19 CFR 351.214(b)(2)(iv)(A) and (C), respectively. Second, Jianglong did not request a new shipper review within one year of reporting its first U.S. entry or shipment, thus failing to satisfy the requirement of 19 CFR 351.214(c). Because Jianglong's new shipper review

² See memorandum entitled, "Small Diameter Graphite Electrodes from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty New Shipper Review; 02/01/2014–08/31/2014" dated August 6, 2015.

³ The scope described in the order refers to the HTSUS subheading 8545.11.0000. We point out that, starting in 2010, imports of small diameter graphite electrodes are classified in the HTSUS under subheading 8545.11.0010 and imports of large diameter graphite electrodes are classified under subheading 8545.11.0020.

⁴ See Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, "Issues and Decision Memorandum for Final Rescission of Antidumping Duty New Shipper Review: Small Diameter Graphite Electrodes from the People's Republic of China" (Issues and Decision Memorandum), dated concurrently with and hereby adopted by this notice.

request does not satisfy these regulatory requirements, we are rescinding the review.⁵

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this new shipper review are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as an appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>, and in the Central Records Unit, B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Enforcement and Compliance Web site at <http://enforcement.trade.gov/frn/index.html>.

Cash Deposit Requirements

Effective upon publication of the final rescission of the new shipper review of Jianglong, we will instruct U.S. Customs and Border Protection (CBP) to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of subject merchandise by Jianglong, in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Cash deposits will be required for exports of subject merchandise by Jianglong entered, or withdrawn from warehouse, for consumption on or after the publication date at the *ad valorem* PRC-wide rate, 159.64 percent.

Assessment Rates

Entries of subject merchandise made by Jianglong covered by this new shipper review are within the POR covered by the administrative review initiated on April 3, 2015 (February 1, 2014 through January 31, 2015).⁶ Because Jianglong's entries are also covered by that administrative review and the POR of the new shipper review is within the POR of the administrative review, we will issue liquidation instructions and assess duties for Jianglong's entries upon completion of the ongoing administrative review. Accordingly, we will instruct CBP to assess antidumping duties on entries for Jianglong at the appropriate rate

⁵ See Issues and Decision Memorandum.

⁶ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 80 FR 18202 (April 3, 2015).

determined in the final results of the administrative review.

Notification to Importers

This notice also serves as a 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.

This new shipper review and notice are in accordance with sections 751(a)(2)(B) and 777(i) of the Act and 19 CFR 351.214(f)(3).

Dated: October 5, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Issues Addressed in the Final Decision Memorandum

Summary
Background
Scope of the Order
Discussion of the Issues
Comment 1: Rescission of the New Shipper Review
Comment 2: The *Bona Fides* of the U.S. Sale
Comment 3: Surrogate Value for Coal Gas Recommendation

[FR Doc. 2015–25984 Filed 10–15–15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE250

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Highly Migratory Species Advisory Subpanel (HMSAS) and Highly Migratory Species Management Team (HMSMT) will hold a Webinar, which is open to the public.

DATES: The Webinar will be held on Tuesday, November 3, 2015, from 1:30 p.m. to 4:30 p.m. Pacific Time, or when business for the day is complete.

ADDRESSES: To attend the webinar, visit <http://www.joinwebinar.com>. Enter the Webinar ID: 135-307-211, and your name and email address (required). Once you have joined the webinar, after logging in to the Webinar, dial this TOLL number (631) 992-3221, enter the Attendee phone audio access code 199-048-743, and enter your audio phone pin (shown after joining the webinar). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback. System requirements for PC-based attendees: Required: Windows® 7, Vista, or XP; for Mac®-based attendees: Required: Mac OS® X 10.5 or newer; and for mobile attendees: Required: iPhone®, iPad®, Android™ phone or Android tablet (See the GoToMeeting Webinar Apps). You may also send an email to Mr. Kris Kleinschmidt or contact him at 503-820-2280 for technical assistance. A listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE., Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Dr. Kit Dahl, Pacific Council; telephone: (503) 820-2422.

SUPPLEMENTARY INFORMATION: The HMSMT and HMSAS will develop recommendations for the North Pacific albacore management strategy evaluation to be conducted by the International Scientific Committee for Tuna and Tuna-Like Species in the North Pacific Ocean. Recommendations may include management objectives, harvest control rules, biological reference points, and evaluation criteria. Recommendations will be forwarded to U.S. government representatives to the planned special meeting of the Western and Central Pacific Fisheries Commission Northern Committee to be held in December 2015.

The HMSAS Chair and the HMSMT Chair will act as co-chairs and comments from the public during the webinar will be received from attendees at their discretion.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820-2280 at least 5 days prior to the meeting date.

Dated: October 13, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-26352 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE237

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Salmon Technical Team (STT), Salmon Advisory Subpanel (SAS), and Model Evaluation Workgroup (MEW) will hold a webinar, which is open to the public.

DATES: The webinar will be held on Wednesday, November 4, 2015, from 1:30 p.m. until business for the day is complete.

ADDRESSES: To attend the webinar, visit: <http://www.gotomeeting.com/online/webinar/join-webinar>. Enter the Webinar ID, which is 142-916-755, and your name and email address (required). After logging in to the webinar, please: dial this TOLL number +1 (914) 614-3221 (not a toll-free number), enter the Attendee phone audio access code 680-582-119, and then enter your audio phone pin (shown after joining the webinar). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback.

(See http://www.pcouncil.org/wp-content/uploads/PFMC_Audio_Diagram_GoToMeeting.pdf). System Requirements for PC-based attendees: Required: Windows® 7, Vista, or XP; for Mac®-based attendees: Required: Mac OS® X 10.5 or newer; and for mobile attendees: iPhone®, iPad®, Android™ phone or Android tablet (See the GoToMeeting Webinar Apps).

You may send an email to kris.kleinschmidt@noaa.gov or contact

him at (503) 820-2280, extension 425 for technical assistance. A public listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Burner, Pacific Council; telephone: (503) 820-2414.

SUPPLEMENTARY INFORMATION: The STT, SAS, and MEW will discuss items on the Pacific Council's November 2016 meeting agenda. Major topics include, but are not limited to: Salmon Methodology Review, Salmon Management Schedule for 2016, Habitat, and 2016 Pacific Halibut Catch Sharing Plan and Management Measures. The STT, SAS, and MEW may also address one or more of the Council's scheduled Administrative Matters. Public comments during the webinar will be received from attendees at the discretion of the STT, SAS, and MEW Chairs.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820-2280, extension 425 at least 5 days prior to the meeting date.

Dated: October 13, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-26349 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Electronic Monitoring Workgroup (EMWG) will meet November 2 and November 3, 2015.

DATES: The meeting will be held on Monday, November 2, 2015, from 1 p.m. to 5 p.m. and on Tuesday, November 3, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Anchorage Marriott Downtown Hotel, 820 W. 7th Ave., Juneau/Haines Room, Anchorage, AK 99501.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501-2252; telephone: (907) 271-2809.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; telephone: (907) 271-2809.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, November 2, 2015 through Tuesday, November 3, 2015

The agenda will include: (a) Update on 2015 cooperative research, (b) Discuss elements of 2016 EM Pre-implementation Program, (c) Review budget, (d) Plan for EM Integration Analysis, (e) Discuss other 2016 EM research, and (f) Other business and scheduling. The Agenda is subject to change, and the latest version will be posted at <http://www.npfmc.org/>

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271-2809 at least 7 working days prior to the meeting date.

Dated: October 13, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-26354 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE247

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings of the South Atlantic Fishery Management Council's Snapper Grouper Advisory Panel (AP) and Information and Education AP.

SUMMARY: The South Atlantic Fishery Management Council (SAFMC) will hold meetings of its Snapper Grouper AP and Information & Education AP in North Charleston, SC.

DATES: The Snapper Grouper AP will meet from 1:30 p.m. on Tuesday, November 3, 2015 until 5 p.m. on Wednesday, November 4, 2015. The Information and Education AP meeting will be held Thursday, November 5, 2015, from 9 a.m. until 5 p.m.

ADDRESSES:

Meeting address: The meetings will be held at the Crowne Plaza Hotel, 4831 Tanger Outlet Blvd., North Charleston, SC 29418; phone: (877) 227-6963 or (843) 744-4422; fax: (843) 744-4472.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571-4366 or toll free: (866) SAFMC-10; fax: (843) 769-4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The items of discussion in the individual meeting agendas are as follows:

Snapper Grouper Advisory Panel Agenda

1. The AP will receive updates on the status of Amendments under development and recently implemented and the October meeting of the SAFMC Scientific and Statistical Committee

2. The AP will review and provide recommendations as appropriate on the following Amendments currently under development:

a. Amendment 37 to the Snapper Grouper Fishery Management Plan (hogfish)

b. Amendment 25 (blueline tilefish, yellowtail snapper, and black sea bass)

c. Amendment 36 (Spawning Special Management Zones)

d. Joint South Atlantic (SA)/Gulf of Mexico (GM) Amendment on South Florida Issues (Yellowtail Snapper Acceptable Biological Catch and Annual Catch Limits & Accountability Measures)

e. Joint SA/GM Charterboat Electronic Reporting Amendment

3. Update on Atlantic Coastal Cooperative Statistics Program proposal for electronic reporting for charter fleet

4. Update on the October 2015 Council Visioning Workshop

Information and Education Advisory Panel Agenda

The Information and Education AP will receive updates on the following and provide recommendations as appropriate:

1. SAFMC System Management Plan—Outreach Sections
2. SAFMC Vision Blueprint for the Snapper Grouper Fishery—Communication Goal
3. SAFMC Technical Documents and Public Input Strategies
4. SAFMC Fishery Citizen Science Initiative
5. Marine Resource Education Program—South East
6. 2016 SAFMC Outreach Projects

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 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: October 13, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-26350 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee (Committee) in St. Thomas, USVI.

DATES AND TIMES: The meeting will be held on Tuesday, November 3, 2015, from 8:30 a.m. to 5:30 p.m. and on Wednesday, November 4, 2015, from 8:30 a.m.–3:00 p.m. These times and the agenda topics described below are subject to change. Refer to the Web page listed below for the most up-to-date meeting agenda.

ADDRESSES: The meeting will be held at the University of the Virgin Islands—St. Thomas, ACC Building 1st Floor

Conference Room, #2 John Brewers Bay, St. Thomas, USVI, 00802.

FOR FURTHER INFORMATION CONTACT: Jessica Snowden, Alternate Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Program, 1315 East-West Highway, Second Floor, Silver Spring, MD 20910; Phone 301-713-3070 x 141; Fax 301-713-3281; Email jessica.snowden@noaa.gov or visit the U.S. IOOS Advisory Committee Web site at <http://www.ioos.noaa.gov/advisorycommittee>.

SUPPLEMENTARY INFORMATION: The Committee was established by the NOAA Administrator as directed by Section 12304 of the Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111-11). The Committee advises the NOAA Administrator and the Interagency Ocean Observation Committee (IOOC) on matters related to the responsibilities and authorities set forth in section 12302 of the Integrated Coastal and Ocean Observation System Act of 2009 and other appropriate matters as the Under Secretary refers to the Committee for review and advice.

The Committee will provide advice on:

- (a) Administration, operation, management, and maintenance of the System;
- (b) expansion and periodic modernization and upgrade of technology components of the System;
- (c) identification of end-user communities, their needs for information provided by the System, and the System's effectiveness in dissemination information to end-user communities and to the general public; and
- (d) any other purpose identified by the Under Secretary of Commerce for Oceans and Atmosphere or the Interagency Ocean Observation Committee.

The meeting will be open to public participation with a 30-minute public comment period on November 3, 2015, from 3:30 p.m. to 4:00 p.m. and on November 4, 2015, from 2:15 p.m. to 2:45 p.m. (check agenda on Web site to confirm time.) The Committee expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by the Designated Federal Official by October 22, 2015 to provide sufficient time for Committee review. Written comments received after

October 22, 2015, will be distributed to the Committee, but may not be reviewed prior to the meeting date. Seats will be available on a first-come, first-served basis.

Matters To Be Considered: The meeting will focus on ongoing committee priorities, including discussions of ICOOS Act Reauthorization, raising IOOS to a national-level program, and increasing engagement with industry. This meeting will also focus specifically on how U.S. IOOS may better address needs of the USVI and better leverage existing partnerships at the local level. The agenda is subject to change. The latest version will be posted at <http://www.ioos.gov/advisorycommittee>.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Jessica Snowden, Alternate Designated Federal Official at 301-713-3070 x 141 by October 22, 2015.

Dated: October 5, 2015.

Chris Cartwright,

Chief Financial Officer, National Ocean Service.

[FR Doc. 2015-26360 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE255

Pacific Fishery Management Council; Public Meeting (Webinar)

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

ACTION: Notice of public meeting (Webinar).

SUMMARY: The Pacific Fishery Management Council (Pacific Council) will convene a Webinar meeting of its Coastal Pelagic Species Advisory Subpanel (CPSAS). The meeting is open to the public.

DATES: The Webinar will be held Monday, November 2, 2015, from 1 p.m. to 2:30 p.m. Pacific Standard Time.

ADDRESSES: To attend the webinar, visit: <http://www.gotomeeting.com/online/webinar/join-webinar>. The Webinar ID and call-in information will be available on the Council's Web site in advance of the meeting.

Council address: Pacific Fishery Management Council, 7700 NE.

Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Kerry Griffin, Staff Officer; telephone: (503) 820-2409.

SUPPLEMENTARY INFORMATION: The primary purpose of the meeting is to discuss agenda items on the November 2015 Pacific Council meeting agenda. Topics may include the Pacific sardine distribution workshop report, anchovy general status, data-limited stock assessments for CPS, and/or methodology review topic selection.

Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the CPSAS's intent to take final action to address the emergency.

Special Accommodations

The public listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt, (503) 820-2280, at least 5 days prior to the meeting date.

Dated: October 13, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-26353 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE249

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Management Team (GMT) will hold a webinar that is open to the public.

DATES: The GMT meeting will be held Thursday, November 5, 2015, from 9 a.m. until 12 p.m.

ADDRESSES: To attend the webinar (1) join the meeting by visiting this link <http://www.gotomeeting.com/online/webinar/join-webinar>; (2) enter the

Webinar ID: 139-525-979, and (3) enter your name and email address (required). After logging in to the webinar, please (1) dial this TOLL number +1 (562) 247-8321 (not a toll-free number); (2) enter the attendee phone audio access code 889-990-126; and (3) then enter your audio phone pin (shown after joining the webinar). Participants are encouraged to use their telephone, as this is the best practice to avoid technical issues and excessive feedback. (See the *PFMC GoToMeeting Audio Diagram for best practices*). Technical Information and System Requirements: PC-based attendees are required to use Windows® 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, Android™ phone or Android tablet (See the *GoToMeeting WebinarApps*).

You may send an email to kris.kleinschmidt@noaa.gov or contact him at (503) 820-2280, extension 425 for technical assistance. A public listening station will also be provided at the Council office.

Council address: Pacific Council, 7700 NE. Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Ames, Pacific Council; telephone: (503) 820-2426.

SUPPLEMENTARY INFORMATION: The primary purpose of the GMT working meeting is to prepare for the November 2015 Pacific Council meeting. The GMT may also address other assignments relating to groundfish management. No management actions will be decided by the GMT. Public comment will be accommodated if time allows, at the discretion of the GMT Chair. The GMT's task will be to develop recommendations for consideration by the Pacific Council at its November 13-19, 2015 meeting in Garden Grove, CA.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The public listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids

should be directed to Mr. Kris Kleinschmidt at (503) 820-2425 at least 5 days prior to the meeting date.

Dated: October 13, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-26351 Filed 10-15-15; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds a product to the Procurement List that will be furnished by the nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: Effective 11/15/2015.

ADDRESSES: Committee for Purchase from People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603-7740, Fax: (703) 603-0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Addition

On 9/4/2015 (80 FR 53501-53502), the Committee for Purchase from People Who Are Blind or Severely Disabled published notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to provide the product and impact of the addition on the current or most recent contractors, the Committee has determined that the product listed below is suitable for procurement by the Federal Government under 41 U.S.C.s 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will furnish the product to the Government.
2. The action will result in authorizing a small entity to furnish the product to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. sections 8501-8506) in connection with the product proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product is added to the Procurement List:

Product

NSN(s)—Product Name(s): 8415-01-644-9620—Gaiter, FREE, Army, Army Tan. Mandatory for: 100% of the requirement of the U.S. Army.

Mandatory Source(s) of Supply: NYSARC, Inc., Seneca-Cayuga Counties Chapter, Waterloo, NY.

Contracting Activity: Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division.

Distribution: C-List.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015-26342 Filed 10-15-15; 8:45 am]

BILLING CODE 6353-01-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0024]

Agency Information Collection Activities; Submission for OMB Review; Comment Request—Notification Requirements for Coal and Wood Burning Appliances

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act ("PRA") of 1995 (44 U.S.C. chapter 35), the Consumer Product Safety Commission ("Commission" or "CPSC") announces that the Commission has submitted to the Office of Management and Budget ("OMB") a request for extension of approval of a collection of information associated with notification requirements for coal and wood burning appliances (OMB No. 3041-0040). In the **Federal Register** of July 30, 2015 (80 FR 45509), the CPSC published a notice to announce the agency's intention to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Written comments on this request for extension of approval of information collection requirements

should be submitted by November 16, 2015.

ADDRESSES: Submit comments about this request by email: OIRA_submission@omb.eop.gov or fax: 202-395-6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at <http://www.regulations.gov>, under Docket No. CPSC-2012-0024.

FOR FURTHER INFORMATION CONTACT: For further information contact: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504-7815, or by email to: rsquibb@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC has submitted the following currently approved collection of information to OMB for extension:

Title: Notification Requirements for Coal and Wood Burning Appliances.

OMB Number: 3041-0040.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of coal and wood burning appliances.

Estimated Number of Respondents: An estimated five submissions annually.

Estimated Time per Response: Three hours per submission.

Total Estimated Annual Burden: 15 hours (5 submissions × 3 hours).

General Description of Collection: 16 CFR part 1406, Coal and Wood Burning Appliances—Notification of Performance and Technical Data requires that manufacturers and importers provide consumers with written notification regarding certain technical and performance information related to safety on each coal and wood burning appliance. Manufacturers are also required to provide to the Commission a copy of the notification to consumers and an explanation of all clearance distances contained in the notification. For existing models, all known manufacturers have complied with the requirements. Accordingly, there is no new burden associated with the requirements of 16 CFR part 1406, except in cases where existing models are changed or new models are introduced. Less than five submissions are estimated annually as a result of new stove models coming into the market or new firms entering the market.

Dated: October 9, 2015.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2015-26333 Filed 10-15-15; 8:45 am]

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0030]

Agency Information Collection Activities; Submission for OMB Review; Comment Request—Testing and Recordkeeping Requirements for Carpets and Rugs

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (“PRA”) of 1995 (44 U.S.C. chapter 35), the Consumer Product Safety Commission (“Commission” or “CPSC”) announces that the Commission has submitted to the Office of Management and Budget (“OMB”) a request for extension of approval of a collection of information associated with the Standard for the Surface Flammability of Carpets and Rugs (16 CFR part 1630) and the Standard for the Surface Flammability of Small Carpets and Rugs (16 CFR part 1631) previously approved under OMB No. 3041-0017. In the **Federal Register** of June 25, 2015 (80 FR 45509), the CPSC published a notice to announce the agency’s intention to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by November 16, 2015.

ADDRESSES: Submit comments about this request by email: OIRA_submission@omb.eop.gov or fax: 202-395-6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at [http://](http://www.regulations.gov)

www.regulations.gov, under Docket No. CPSC-2012-0030.

FOR FURTHER INFORMATION CONTACT: For further information contact: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504-7815, or by email to: rsquibb@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC has submitted the following currently approved collection of information to OMB for extension:

Title: Safety Standard for the Flammability of Carpets and Rugs and Standard for the Flammability of Small Carpets and Rugs.

OMB Number: 3041-0017.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of carpets and rugs.

Estimated Number of Respondents: 120 firms issue guarantees of compliance under the carpet and rug flammability standards. Based on information obtained from industry, the actual number of tests performed to affirm the guarantees of compliance may vary from one to 200, depending on the number of carpet styles and annual production volume. To estimate a burden, a midpoint of 100 tests per year per firm is used.

Estimated Time per Response: 2.5 hours to conduct each test, and to establish and maintain test records.

Total Estimated Annual Burden: 30,000 hours (120 firms × 100 tests × 2.5 hours).

General Description of Collection: The Standard for the Surface Flammability of Carpets and Rugs (16 CFR part 1630) and the Standard for the Surface Flammability of Small Carpets and Rugs (16 CFR part 1631) establish requirements for testing and recordkeeping for manufacturers and importers who furnish guarantees subject to the carpet and rug flammability standards.

Dated: October 9, 2015.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2015-26334 Filed 10-15-15; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE**Office of the Secretary**

[Docket ID: DoD–2015–OS–0098]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness/National Security Education Program, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Under Secretary of Defense for Personnel and Readiness/National Security Education Program announces a proposed public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by December 15, 2015.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the

instructions at <http://www.regulations.gov> for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Under Secretary of Defense for Personnel and Readiness/National Security Education Program, Attn: Dr. Michael Nugent, P.O. Box 12221, Arlington, VA 22209–2221, or call at (703) 696–5673.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: National Language Service Corps; DD Forms 2932, 2933, and 2934; OMB Control Number 0704–0449.

Needs and Uses: The information collection requirement is necessary to identify individuals with language and special skills who potentially qualify for employment or service opportunities in the public section during periods of national need or emergency.

Affected Public: Individuals or households.

Annual Burden Hours: 167 hours.

Number of Respondents: 1,500.

Responses per Respondent: 3.

Annual Responses: 4,500.

Average Burden per Response: 16.24 minutes.

Frequency: On occasion.

The DD Form 2932, *National Language Service Corps (NLSC) Pilot Application*, is the initial document used to collect information from members of the public. The NLSC Pilot Application form contains a brief set of screening questions and provides background data on where the applicant learned the foreign language and whether the applicant has used the language professionally. Applicants fill this out for basic information (age, citizenship, Foreign Language), and if they meet eligibility criteria, they proceed to the supplemental documents. Members are required to renew their DD Form 2932 information every four years. Renewing applicants are in addition to those initially applying.

The supplemental documents are used to determine eligibility for membership in the NLSC. The DD Form 2934, *National Language Service Corps (NLSC) Global Language Self-Assessment*, provides an overall assessment of the applicant's foreign language ability. The DD Form 2933, *National Language Service Corps (NLSC) Pilot Detailed Skills Self-Assessment*, is a detailed description of

the applicant's skills with respect to specific foreign language tasks. These two supplemental documents are used in conjunction for the certification of language skills for entry into the NLSC and quality assurance of certification.

The information collected in the application and the supplemental documents is used solely by the NLSC.

Dated: October 9, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–26338 Filed 10–15–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Office of the Secretary****Membership of the Performance Review Board**

AGENCY: Office of the Secretary of Defense (OSD), DoD.

ACTION: Notice of board membership.

SUMMARY: This notice announces the appointment of the Department of Defense, Fourth Estate, Performance Review Board (PRB) members, to include the Office of the Secretary of Defense, Joint Staff, Defense Field Activities, U.S. Court of Appeals for the Armed Forces, and the following Defense Agencies: Defense Advanced Research Projects Agency, Defense Commissary Agency, Defense Contract Audit Agency, Defense Contract Management Agency, Defense Finance and Accounting Service, Defense Health Agency, Defense Information Systems Agency, Defense Legal Services Agency, Defense Logistics Agency, Defense Prisoners of War/Missing in Action Accounting Agency, Defense Security Cooperation Agency, Defense Threat Reduction Agency, Missile Defense Agency, and Pentagon Force Protection Agency. The PRB shall provide fair and impartial review of Senior Executive Service and Senior Professional performance appraisals and make recommendations regarding performance ratings and performance awards to the Deputy Secretary of Defense.

DATES: *Effective Date:* September 12, 2015.

FOR FURTHER INFORMATION CONTACT: Michael L. Watson, Assistant Director for Office of the Secretary of Defense Senior Executive Management Office, Office of the Deputy Chief Management Officer, Department of Defense, (703) 693–8373.

SUPPLEMENTARY INFORMATION: The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). In accordance with 5 U.S.C. 4314(c)(4), the following executives are appointed to the Office of the Secretary of Defense PRB with specific PRB panel assignments being made from this group. Executives listed will serve a one-year renewable term, effective September 12, 2015.

Office of the Secretary of Defense

Authorizing Official—Robert O. Work,
Deputy Secretary of Defense

Principal Executive Representative—
Michael L. Rhodes

Chairperson—Bonnie M. Hammersley

PRB Panel Members

AINSWORTH, THOMAS W
ARMSTRONG, JR, JAMES E
BEEBE, MATTHEW R
BRENNAN, KENNETH M
BRUMER, ERIC Y
CALLAHAN, TIMOTHY P
CARDENAS, MANUEL A
CASE, EDWARD J
CONDON, CHRISTINE M
DIGIOVANNI, FRANK C
EDWARDS, ROBERT A
GEORGE, SUSAN E
HEBERT, LERNES J
KOFFSKY, PAUL S
KOSAK, CHARLES P
LEWIS, ALAN D
MCKAY, TERESA A
MCKENZIE, DONALD J
MITCHELL, PAMELA S
MORGAN, ANDREW S
MORGAN, NANCY E
PACKARD, DOUGLAS W
PETERS, PAUL D
RICHARDSON, SANDRA V
SCHLEIEN, STEVEN L
SCHLESS, SCOTT R
SHEPHARD, MONICA R
SNAVELY-DIXON, MARY M
SPJUT, GARY B
TIMERMAN, STUART F
VANNESS, JAMES G
WALSH, JENNIFER C
WEATHERINGTON, BRIG GEN MARK
E
WHITMAN, BRYAN G
WORM, JAMES A
YOUNG, PATRICIA M

Dated: October 9, 2015.

Aaron Siegel,

*Alternate OSD Federal Register Liaison
Officer, Department of Defense.*

[FR Doc. 2015-26337 Filed 10-15-15; 8:45 am]

BILLING CODE 5001-06-P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Notice

AGENCY: Defense Nuclear Facilities
Safety Board.

ACTION: Notice of public business
meeting.

SUMMARY: Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given of the Defense Nuclear Facilities Safety Board’s (Board) public business meeting described below.

DATES: *Time and Date of Meeting:* 9 a.m.–12:15 p.m., November 10, 2015.

ADDRESSES: *Place:* Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 352, Washington, DC 20004–2901.

FOR FURTHER INFORMATION CONTACT:

Mark Welch, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

Status: Open.

Matters to be Considered: This public business meeting will be conducted pursuant to the Government in the Sunshine Act, the Board’s implementing regulations for the Government in the Sunshine Act, and the Board’s Operating Procedures dated August 2015. The meeting will proceed in accordance with the previously approved business meeting agenda entitled “DNFSB Work Plans and Staffing Plan for Fiscal Year 2016.” The Chairman and the Board Members will provide opening remarks followed by presentations from the Office of the Technical Director (OTD) staff concerning an overview of technical staff work plan activities and crosscutting issues. The Board will then engage in discussions among themselves on crosscutting issues. OTD staff will then provide a presentation on technical staff work related to National Nuclear Security Administration (NNSA) and Department of Energy Environmental Management (EM) programs. The Board is expected to conduct discussions among themselves concerning NNSA and EM program issues and Board staff priorities. The Board will then receive comments from the public followed by Board Member remarks. The Chairman will then provide closing remarks.

The business meeting agenda is posted on the Board’s public Web site. The public is invited to view this business meeting and provide comments. A transcript of the business

meeting, along with a DVD video recording, will be made available by the Board for inspection and viewing by the public at the Board’s Washington office. The Board specifically reserves its right to further schedule and otherwise regulate the course of the business meeting, to recess, reconvene, postpone, or adjourn the meeting, and otherwise exercise its rights under the Atomic Energy Act, the Government in the Sunshine Act and the Board’s Operating Procedures.

Dated: October 9, 2015.

Joyce L. Connery,
Chairman.

[FR Doc. 2015-26376 Filed 10-14-15; 11:15 am]

BILLING CODE 3670-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2015-ICCD-0122]

Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Non- Title IV Revenue Requirements (90/10)

AGENCY: Federal Student Aid (FSA),
Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 15, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2015-ICCD-0122. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

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: Student Assistance General Provisions—Non-Title IV Revenue Requirements (90/10).

OMB Control Number: 1845-0096.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 3,360.

Total Estimated Number of Annual Burden Hours: 5,040.

Abstract: As enacted by the Higher Education Opportunity Act (Pub. L. 110-315), the regulations in 34 CFR 668.28 provide that a proprietary institution must derive at least 10% of its annual revenue from sources other than Title IV, HEA funds, sanctions for failing to meet this requirement, and otherwise implement the statute by (1) specifying a Net Present Value (NPV) formula used to establish the revenue for institutional loans, (2) providing an administratively easier alternative to the NPV calculation, and (3) describing more fully the non-Title IV eligible programs from which revenue may be counted for 90/10 purposes. The regulations require an institution to disclose in a footnote to its audited financial statements the amounts of Federal and non-Federal revenues, by

category, that it used in calculating its 90/10 ratio (see section 487(d) of the HEA). This is a request to extend the information collection that identifies the reporting burden for this regulation.

Dated: October 13, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015-26343 Filed 10-15-15; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2015-ICCD-0123]

Agency Information Collection Activities; Comment Request; Educational Quality Through Innovative Partnerships (EQUIP) Experimental Sites Initiative

AGENCY: Federal Student Aid (FSA), 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 December 15, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2015-ICCD-0123. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

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: Educational Quality through Innovative Partnerships (EQUIP) Experimental Sites Initiative.

OMB Control Number: 1845-NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Private Sector, State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 20.

Total Estimated Number of Annual Burden Hours: 1,500.

Abstract: The Department of Education (the Department) is requesting this new information collection package to provide for a series of questions that are components of the selection process for a new Federal Student Aid experimental site project. The Educational Quality through Innovative Partnerships (EQUIP) project is being undertaken in order to advance the Department's understanding of how to best increase access to high quality innovative programs in higher education. An invitation to participate and an explanation of this proposed experimental site was published separately in the **Federal Register**. This experimental site project is designed to explore ways to increase access for low-income students to high-quality innovate programs in higher education through the engagement of institutions of higher education (IHEs) with non-IHE providers and quality assurance entities that can develop new quality assurance processes for student and taxpayer

protection. The data and information collected can provide valuable guidance for the Department in determining future policy in these areas.

Dated: October 13, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015-26344 Filed 10-15-15; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12514-074]

Northern Indiana Public Service Company, Notice of Availability of Draft Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC's) regulations, 18 Code of Federal Regulations (CFR) Part 380, the Office of Energy Projects has reviewed Northern Indiana Public Service Company's application for amendment of the license for the Norway-Oakdale Hydroelectric Project (FERC Project No. 12514-074), on the Tippecanoe River near the city of Monticello in Carroll and White Counties, Indiana. The project does not occupy any federal lands.

Staff prepared a draft environmental assessment (EA) to analyze the potential environmental effects of implementing the proposed modified definition of abnormal flow conditions, as required by article 405 of the current license (issued October 2, 2007), that would be included in a revised article 403, which defines the operation of the project. Staff concludes that authorizing the amendment, with staff's recommended modification to the definition of abnormal river conditions, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at www.ferc.gov using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, 202-502-8659.

You may also register online at www.ferc.gov/docs-filing/esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. Comments may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site 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. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and five copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. For further information, contact Rebecca Martin by telephone at 202-502-6012 or Mark Pawlowski at 202-502-6052.

Dated: October 9, 2015.

Kimberly D. Bose,
Secretary.

[FR Doc. 2015-26384 Filed 10-15-15; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9023-5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7146 or <http://www2.epa.gov/nepa>. Weekly receipt of Environmental Impact Statements (EISs) Filed 10/05/2015 Through 10/09/2015 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxnodengn.epa.gov/cdx-nepa-public/action/eis/search>.

EIS No. 20150289, Revised Draft, USAF, GU, Divert Activities and Exercises, Commonwealth of the Northern Mariana Islands, Comment Period

Ends: 11/30/2015, Contact: Mark Petersen 808-449-1078.
EIS No. 20150290, Final, USCG, MARAD, NY, Port Ambrose Deepwater Port Application, Review Period Ends: 11/30/2015, Contact: Roddy C. Bachman 202-372-1451.

Amended Notices

EIS No. 20150231, Draft, USACE, CT, PROGRAMMATIC-Long Island Sound Dredged Material Management Plan, Comment Period Ends: 10/16/2015, Contact: Meghan Quinn 978-318-8179. Revision to the FR Notice Published 08/21/2015; Extended Comment Period from 10/05/2015 to 10/16/2015.

EIS No. 20150253, Draft, USACE, PR, Caño Martín Peña Ecosystem Restoration Project, Comment Period Ends: 11/09/2015, Contact: Jim Suggs 904-232-1018. Revision to the FR Notice Published 09/11/2015; Extending Comment Period from 10/26/2015 to 11/09/2015.

Dated: October 13, 2015.

Karin Leff,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015-26348 Filed 10-15-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-SFUND-2010-0763; FRL-9935-84-OSWER]

Proposed Information Collection Request; Comment Request; Hazardous Chemical Reporting: The Emergency and Hazardous Chemical Inventory Forms (Tier I and Tier II)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), "Hazardous Chemical Reporting: The Emergency and Hazardous Chemical Inventory Forms (Tier I and Tier II)" (EPA ICR No. 2436.03, OMB Control No. 2050-0206) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through March 31, 2016. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it

displays a currently valid OMB control number.

DATES: Comments must be submitted on or before December 15, 2015.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-SFUND-2010-0763 referencing the Docket ID numbers provided for each item in the text, online using www.regulations.gov (our preferred method), by email to or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564-8019; fax number: (202) 564-2620; email address: jacob.sicy@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Sections 311 and 312 of the Emergency Planning and Community Right-to-Know Act (EPCRA) apply to the owner or operator of any facility that is required to prepare or have available a Material Safety Data Sheet (MSDS) for a hazardous chemical under the Occupational Safety and Health Act of 1970 and its implementing regulations. Under section 311 of EPCRA, these facilities are required to submit MSDS to the State Emergency Response Commission (SERC), the Local Emergency Planning Committee (LEPC), and the local fire department for each hazardous chemical stored on-site in a quantity greater than the reporting threshold. Alternatively, a list of subject chemicals, grouped by hazard type, may be submitted. Section 312 of EPCRA requires owners and operators of facilities subject to section 311 to annually report the inventories of those chemicals reported under section 311. The Environmental Protection Agency (EPA) is required to publish two emergency and hazardous chemical inventory forms, known as "Tier I" and "Tier II," for use by these facilities. These forms were first published in October 1987 and amended in July 1990. On July 13, 2012, EPA further revised these forms to add some new data elements that would be useful for local emergency planners and responders. This is the renewal of the information collection request which was previously approved by OMB in ICR No. 2436.02. In ICR 2436.02, EPA estimated that after the initial reporting of the new data elements, which was reporting year 2013, that it would only take 0.25 hours per facility to review the new data elements and revise if necessary. Most of the new data elements were added to page one of the Tier II form, which include contact information for facility emergency coordinator; Tier II information; whether facility is manned or unmanned; if the facility is subject to EPCRA Section 302 or CAA Section 112(r) (Risk Management Program) etc. EPA do not expect these data to change annually. However, we estimated that minimal burden may be incurred for reviewing these data annually and revising the information as necessary.

Form Numbers: 8700-30, Emergency and Hazardous Chemical Inventory Form.

Respondents/Affected Entities: Facilities that are required to prepare or have available a Material Safety Data Sheet (MSDS) for any hazardous chemicals present at the facility above the reporting thresholds specified in the regulations at 40 CFR part 370. These facilities are required to submit a hazardous chemical inventory form, to the SERC, LEPC and the local fire department with jurisdiction over the facility, by March 1 annually.

Respondent's Obligation to Respond: Mandatory under Section 312 of EPCRA.

Estimated Number of Respondents: Approximately 390,000 facility respondents (120,000 manufacturers and 270,000 non-manufacturers) and 3,052 SERCs and LEPCs (total).

Frequency of Response: Annually.

Total Estimated Burden: 97,500 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total Estimated Cost: \$5,675,675 per year. There are no annualized capital or operation & maintenance costs expected during this ICR period.

Changes in Estimates: There is a decrease of 195,000 hours in the total estimated facility respondent burden compared with the ICR currently approved by OMB. This decrease is due to facility incurring minor burden for reviewing and updating previously reported data mainly on page one of the Tier II inventory form.

Dated: September 16, 2015.

Reggie Cheatham,

Director, Office of Emergency Management.

[FR Doc. 2015-26406 Filed 10-15-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2013-0677; FRL-9935-75]

Receipt of Test Data Under the Toxic Substances Control Act

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 the Toxic Substances Control Act (TSCA). As required by TSCA, this document identifies each chemical substance and/or mixture for which test data have been received; the uses or intended uses of such chemical substance and/or mixture; and describes the nature of the

test data received. Each chemical substance and/or mixture related to this announcement is identified in Unit I. under **SUPPLEMENTARY INFORMATION.**

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; 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. Chemical Substances and/or Mixtures

Information about the following chemical substances and/or mixtures is provided in Unit IV.: *D-erythro-hex-2-enonic acid, gamma-lactone, monosodium salt.* (CAS Number 6381-77-7).

II. Federal Register Publication Requirement

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 TSCA section 4 (15 U.S.C. 2603).

III. Docket Information

A docket, identified by the docket identification (ID) number EPA-HQ-OPPT-2013-0677, has been established for this **Federal Register** document that announces the receipt of data. Upon EPA's completion of its quality assurance review, the test data received will be added to the docket for the TSCA section 4 test rule that required the test data. Use the docket ID number provided in Unit IV. to access the test data in the docket for the related TSCA section 4 test rule.

The docket for this **Federal Register** document and the docket for each related TSCA section 4 test rule is available electronically at <http://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton 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>.

IV. Test Data Received

This unit contains the information required by TSCA section 4(d) for the test data received by EPA. *D-erythro-hex-2-enonic acid, gamma-lactone, monosodium salt.* (CAS Number 6381-77-7).

1. *Chemical Use(s):* Antioxidant in food applications for which the vitamin activity of ascorbic acid (Vitamin C) is not required. Specifically, the compound is most frequently used to develop and retain the coloring and taste in meat products. It is also used for seafood products, fruit, and vegetable preservation, in beverages, and as a developing agent in photographic applications.

2. *Applicable Test Rule:* Chemical testing requirements for second group of high production volume chemicals (HPV2), 40 CFR 799.5087.

3. *Test Data Received:* The following listing describes the nature of the test data received. The test data will be added to the docket for the applicable TSCA section 4 test rule and can be found by referencing the docket ID number provided. EPA reviews of test data will be added to the same docket upon completion.

n-Octanol/Water Partition Coefficient (A4). The docket ID number assigned to this data is EPA-HQ-OPPT-2007-0531.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: October 8, 2015.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2015-26394 Filed 10-15-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0022; FRL-9934-87]

Pesticide Product Registration; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before November 16, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0022 and the File Symbol or Registration Number of interest as shown in the body of this document, 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 Confidential Business Information (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>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main 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. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or email. Clearly mark the part or all of the information that

you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

1. *EPA File Symbol:* 100-RLTN. *Docket ID number:* EPA-HQ-OPP-2015-0589. *Applicant:* Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419. *Active ingredient:* 3.41% bicyclopyrone & 23.16% bromoxynil octanoate. *Product type:* Herbicide. *Proposed Use:* Wheat & barley. *Contact:* RD.

2. *EPA Registration Numbers:* 100-1017, 100-993, and 100-1103. *Docket ID Number:* EPA-HQ-OPP-2015-0629. *Applicant:* Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. *Active Ingredient:* Fomesafen. *Product Type:* Herbicide. *Proposed Use:* Vegetable, tuberous and corm, subgroup 1C; vegetable, legume, Group 6; and berry, low growing subgroup 13-07G except cranberry. *Contact:* RD.

3. *EPA Registration Number:* 100-1098. *Docket ID number:* EPA-HQ-OPP-2014-0822. *Applicant:* Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. *Active ingredient:* Azoxystrobin. *Product type:* Fungicide. *Proposed use:* Quinoa, grain. *Contact:* RD.

4. *EPA Registration Numbers:* 100-1178, 100-1324 and 100-617. *Docket ID number:* EPA-HQ-OPP-2014-0788. *Applicant:* Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. *Active ingredient:* Propiconazole.

Product type: Fungicide. *Proposed use:* Quinoa, grain. *Contact:* RD.

5. *EPA Registration Numbers:* 5481-433 and 5481-429. *Docket ID number:* EPA-HQ-OPP-2014-0769. *Applicant:* AMVAC Chemical Corporation, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660. *Active ingredient:* 1-naphthaleneacetic acid ester. *Product type:* Fungicide. *Proposed use:* Pomegranate. *Contact:* RD.

6. *EPA Registration Number:* 6836-107. *Docket ID number:* EPA-HQ-OPP-2015-0558. *Applicant:* Lonza, Inc., 90 Boroline Road, Allendale, NJ 07401. *Active ingredient:* Metaldehyde. *Product type:* Molluscicide. *Proposed Use:* Wheat; beet, garden; rutabaga; turnip; hop. *Contact:* RD.

7. *EPA Registration Number:* 62719-499, 62719-611. *Docket ID number:* EPA-HQ-OPP-2014-0879. *Applicant:* Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. *Active ingredient:* Penoxsulam. *Product type:* Herbicide. *Proposed use:* Pome Fruit Group 11-10, Stone Fruit Group 12-12, Small Fruit vine Climbing Subgroup 13-07F, Olive, Pomegranate and Crop Group Conversion for Tree Nut group 14-12. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 8, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015-26393 Filed 10-15-15; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[3060-0270]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the

information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 15, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060-0270.

Title: Section 90.443, Content of Station Records.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 63,375 respondents; 63,375 responses.

Estimated Time per Response: .25 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. Section 303(j), as amended.

Total Annual Burden: 15,844 hours. *Annual Cost Burden:* No cost.

Privacy Act Impact Assessment: No impact(s).

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

Needs and Uses: Section 90.443(b) requires that each licensee of a station shall maintain records for all stations by

providing the dates and pertinent details of any maintenance performed on station equipment, along with the name and address of the service technician who did the work. If all maintenance is performed by the same technician or service company, the name and address need be entered only once in the station records.

Section 90.443(c) requires that at least one licensee participating in the cost arrangement must maintain cost sharing records.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015-26304 Filed 10-15-15; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY: Federal Maritime Commission.

TIME AND DATE: October 21, 2015; 10 a.m.

PLACE: 800 N. Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The first portion of the meeting will be held in Open Session; the second in Closed Session.

Matters To Be Considered

Open Session

1. Docket No. 13-05: Amendments to Regulations Governing Ocean Transportation Intermediary Licensing and Financial Responsibility Requirements, and General Duties
2. Briefing on FMC Information Technology Modernization
3. Briefing on FMC Continuity of Operations Plan
4. Briefing on U.S.-Japan Maritime Discussions

Closed Session

1. Service Contracts and Non-Vessel-Operating Common Carrier Service Arrangements—Regulatory Review

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523 5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2015-26474 Filed 10-14-15; 4:15 pm]

BILLING CODE 6731-AA-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC seeks public comments on its proposal to extend, for three years, the current PRA clearance for information collection requirements contained in the rules and regulations under the Health Breach Notification Rule. This clearance expires on March 31, 2016.

DATES: Comments must be received on or before December 15, 2015.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the **SUPPLEMENTARY INFORMATION** section below. Write "Health Breach Notification Rule, PRA Comments, P-125402" on your comment, and file your comment online at <https://ftcpublish.commentworks.com/ftc/healthbreachnotificationpra> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the collection of information and supporting documentation should be addressed to Cora Tung Han, 202-326-2441, Attorney, Privacy & Identity Protection, Bureau of Consumer Protection, 600 Pennsylvania Ave. NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (the Recovery Act or the Act) into law. The Act included provisions to advance the use of health information technology and, at the same time, strengthen privacy and security protections for health information. The Act required the FTC to adopt a rule implementing the breach notification requirements applicable to vendors of personal health records, "PHR related entities,"¹ and third party

¹ "PHR related entity" means an entity, other than a HIPAA-covered entity or an entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity, that: (1) Offers products

service providers, and the Commission issued a final rule on August 25, 2009. 74 FR 42962.

The Health Breach Notification Rule (Rule), 16 CFR part 318, requires vendors of personal health records and PHR related entities to provide: (1) Notice to consumers whose unsecured personally identifiable health information has been breached; and (2) notice to the Commission. The Rule only applies to electronic health records and does not include recordkeeping requirements. The Rule requires third party service providers (*i.e.*, those companies that provide services such as billing or data storage) to vendors of personal health records and PHR related entities to provide notification to such vendors and PHR related entities following the discovery of a breach. To notify the FTC of a breach, the Commission developed a form, which is posted at www.ftc.gov/healthbreach, for entities subject to the rule to complete and return to the agency.

These notification requirements are subject to the provisions of the PRA, 44 U.S.C. Chapter 35. Under the PRA, federal agencies must get OMB approval for each collection of information they conduct, sponsor, or require. "Collection of information" means agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by Section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing PRA clearance for the information collection requirements associated with the Commission's rules and regulations under the Health Breach Notification Rule (or Rule), 16 CFR part 318 (OMB Control Number 3084-0150).

The FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond. All

or services through the Web site of a vendor of personal health records; (2) offers products or services through the Web sites of HIPAA-covered entities that offer individuals personal health records; or (3) accesses information in a personal health record or sends information to a personal health record. 16 CFR 318.2(f).

comments must be received on or before December 15, 2015.

In the Commission's view, it has maximized the practical utility of the breach notification requirements in the Rule, consistent with the requirements of the Recovery Act. Under the Rule, consumers whose information has been affected by a breach of security receive notice of it "without unreasonable delay and in no case later than 60 calendar days" after discovery of the breach. Among other information, the notices must provide consumers with steps they can take to protect themselves from harm. Moreover, the breach notice requirements encourage entities to safeguard the information of their customers, thereby potentially reducing the incidence of harm.

The form entities must use to inform the Commission of a security breach requests minimal information, mostly as replies to check boxes; thus, entities do not require extensive time to complete it. For breaches involving the health information of 500 or more individuals, entities must notify the Commission as soon as possible, and in any event no later than ten business days after discovering the breach. Breaches involving the information of fewer than 500 individuals may be reported in an annual submission that includes all breaches within the calendar year that fall within this category. The form serves the Commission by providing the agency with information about breaches occurring in the PHR industry.

The Commission inputs the information it receives from entities into a database that the Commission updates periodically. The Commission makes certain information about these breaches available to the public. This publicly-available information serves businesses and the public. It provides businesses with information about potential causes of data breaches, which is particularly helpful to those setting up data security procedures. It also provides the public with information about the extent of data breaches. Thus, in the Commission's view, the Rule and form have significant practical utility.

Pursuant to § 318.5 of the Rule, entities must notify the FTC "according to instructions at the Federal Trade Commission's Web site." In 2009, the Commission indicated that "[d]ue to security concerns associated with email transmission, the Commission will not accept emailed forms at this time."² The Commission now offers a secure online method for receiving these notices, and instructions are on the form entities should use for notification,

which is available on the FTC's Web site. Alternatively entities may continue to print and send the form to a designated FTC official by courier or overnight mail.

Burden Estimates

The PRA burden of the Rule's requirements depends on a variety of factors, including the number of covered firms; the percentage of such firms that will experience a breach requiring further investigation and, if necessary, the sending of breach notices; and the number of consumers notified. The annual hours and cost estimates below likely overstate the burden because, among other things, they assume, though it is not necessarily so, that all breaches subject to the Rule's notification requirements will be required to take all of the steps described below.

At the time the Rule was issued, insufficient data was available about the incidence of breaches in the PHR industry. Accordingly, staff based its burden estimate on data pertaining to private sector breaches across multiple industries. Staff estimated that there would be 11 breaches per year requiring notification of 232,000 consumers.³

As described above, the Rule requires covered entities that have suffered a breach to notify the Commission. Since the Rule has now been in effect for over five years,⁴ staff is now able to base the burden estimate on the actual notifications received from covered entities, which include the number of consumers notified. Accordingly, staff has used this information to update its burden estimate.

On average, about 2,500 consumers per year received notifications over the years 2010 and 2011. In 2012 and 2013, between 4,000 and 5,000 consumers received notifications each year. In 2014, approximately 17,993 consumers received notifications. In light of this upwards trend, staff bases its current burden estimate on an assumed two breach incidents per year that, together, require the notification of approximately 40,000 consumers. This estimate will likely overstate the burden; however, as consumers increasingly download their information into personal health records,⁵ staff anticipates that the number of affected consumers will increase.

Estimated Annual Hours Burden: 3,267.

³ 74 FR at 42977.

⁴ The rule became effective on September 24, 2009. Full compliance was required by February 22, 2010.

⁵ See e.g., <http://www.va.gov/bluebutton/>.

As explained in more detail within the next section, FTC staff projects that covered firms will require on average, per breach, 100 hours of employee labor to determine what information has been breached, identify the affected customers, prepare the breach notice, and make the required report to the Commission. Based on an estimated 2 breaches per year, yearly hourly burden would be 200 hours. Additionally, staff expects covered firms will require 3,067 annual hours (1,067 hours of telephone operator time + 2000 hours of information processor time) to process calls they may receive in the event of a data breach. See footnote 8 *infra*.

Estimated Annual Labor Costs: \$61,764.

FTC staff projects that covered firms will require on average, per breach, 100 hours of employee labor to determine what information has been breached, identify the affected customers, prepare the breach notice, and make the required report to the Commission, at an estimated cost of \$5,732⁶ (staff assumes that outside services of a forensic expert will also be required and those services are separately accounted for under "Estimated Annual Non-Labor Costs" below). Based on an estimated 2 breaches per year, the annual employee labor cost burden for affected entities to perform these tasks is \$11,464.⁷

Additionally, covered entities will incur labor costs associated with processing calls they may receive in the event of a data breach. The rule requires that covered entities that fail to contact 10 or more consumers because of insufficient or out-of-date contact information must provide substitute

⁶ Hourly wages throughout this document are based on mean hourly wages found at <http://www.bls.gov/news.release/ocwage.htm> ("Occupational Employment and Wages—May 2014," U.S. Department of Labor, released March 2015, Table 1 ("National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2014").

The breakdown of labor hours and costs is as follows: 50 hours of computer and information systems managerial time at approximately \$66 per hour; 12 hours of marketing manager time at \$66 per hour; 33 hours of computer programmer time at \$40 per hour; and 5 hours of legal staff time at \$64 per hour.

⁷ Labor hours and costs pertaining to reporting to the Commission are subsumed within this total. Specifically, staff estimates that covered firms will require per breach, on average, 1 hour of employee labor at an approximate cost of \$65 to complete the required form. This is composed of 30 minutes of marketing managerial time at \$66 per hour, and 30 minutes of legal staff time at \$64 per hour, with the hourly rates based on the above-referenced Department of Labor table. See note 6, *supra*. Thus, based on 2 breaches per year for which notification may be required, the cumulative annual-hours burden for covered entities to complete the notification to the Commission is 2 hours and the annual labor cost is approximately \$130.00.

² 74 FR at 42975.

notice through either a clear and conspicuous posting on their Web site or media notice. Such substitute notice must include a toll-free number for the purpose of allowing a consumer to learn whether or not his/her information was affected by the breach.

Individuals contacted directly will have already received this information. Staff estimates that no more than 10 percent of affected consumers will utilize the offered toll-free number. Thus, of the 40,000 consumers affected by a breach annually, staff estimates that 4,000 may call the companies over the 90 days they are required to provide such access. Staff additionally projects that 4,000 additional consumers who are not affected by the breach will also call the companies during this period. Staff estimates that processing all 8,000 calls will require an average of 3,067 hours of employee labor at a cost of \$50,300.⁸

Accordingly, estimated cumulative annual labor costs, excluding outside forensic services, is \$62,000.

Estimated Annual Capital and other Non-Labor Costs: \$49,960.

Commission staff anticipates that capital and other non-labor costs associated with the Rule will consist of the following:

1. The services of a forensic expert in investigating the breach;
2. notification of consumers via email, mail, web posting, or media; and
3. the cost of setting up a toll-free number, if needed.

Staff estimates that covered firms (breached entities) will require 30 hours of a forensic expert's time, at a cumulative cost of \$3,960 for each breach. This is the product of hourly wages of an information security analyst (\$44), tripled to reflect profits and overhead for an outside consultant (\$132), and multiplied by 30 hours. Based on the estimate that there will be 2 breaches per year, the annual cost associated with the services of an outside forensic expert is \$7,920.

As explained above, staff estimates that an average of 40,000 consumers per year will receive a breach notification. Given the online relationship between consumers and vendors of personal health records and PHR related entities, most notifications will be made by

⁸ This assumes telephone operator time of 8 minutes per call and information processor time of 15 minutes per call. The cost estimate above is arrived at as follows: 1,067 hours of telephone operator time (8 minutes per call × 8,000 calls) at \$19 per hour, and 2000 hours of information processor time (15 minutes per call × 8,000 calls) at \$15 per hour.

email and the cost of such notifications will be minimal.⁹

In some cases, however, vendors of personal health records and PHR related entities will need to notify individuals by postal mail, either because these individuals have asked for such notification, or because the email addresses of these individuals are not current or not working. Staff estimates that the cost of a mailed notice is \$0.06 for the paper and envelope, and \$0.49 for a first class stamp. Assuming that vendors of personal health records and PHR related entities will need to notify by postal mail 10 percent of the 40,000 customers whose information is breached, the estimated cost of this notification will be \$2,200 per year.¹⁰

In addition, vendors of personal health records and PHR related entities sometimes may need to notify consumers by posting a message on their home page, or by providing media notice. Based on a recent study on data breach costs, staff estimates the cost of providing notice via Web site posting to be \$0.06 per breached record, and the cost of providing notice via published media to be \$0.03 per breached record.¹¹ Applied to the above-stated estimate of 40,000 affected consumers, the estimated total annual cost of Web site notice will be \$2,400, and the estimated total annual cost of media notice will be \$1,200, yielding an estimated total annual cost for all forms of notice to consumers of \$5,800.

Finally, staff estimates that the cost of providing a toll-free number will depend on the costs associated with T1 lines sufficient to handle the projected call volume and the cost of obtaining a toll-free telephone number.¹² Based on industry research, staff projects that affected entities may need two T1 lines

⁹ See National Do Not Email Registry, A Report to Congress, June 2004 n.93, available at www.ftc.gov/reports/dneregistry/report.pdf.

¹⁰ As mentioned above, covered entities will also need to notify the Commission either through an online process or via mail. Staff estimates the non-labor costs for this notification to be negligible.

¹¹ Ponemon Institute, 2006 Annual Study: Cost of a Data Breach, Understanding Financial Impact, Customer Turnover, and Preventative Solutions, Table 2. In studies conducted for subsequent years, the Ponemon Institute does not report this level of detail.

¹² Staff included costs associated with obtaining a T1 line (a specific type of telephone line that can carry more data than traditional telephone lines) in its initial estimate in 2009, but did not include these costs in its most recent estimate based on the low number of consumers notified pursuant to the Rule in 2010 and 2011. Since staff's current estimate includes larger projected call volumes, however, staff has again included these costs. Staff recognizes that this likely overstates the burden because entities may already have these services in place and/or they may not all be necessary depending on how many consumers are affected.

at a cost of \$9,000 for the 90 day period.¹³ In addition, staff estimates the cost of obtaining a dedicated toll-free line to be \$4,540 per month. Accordingly, staff projects that the cost of obtaining two toll-free lines for 90 days will be \$27,240,¹⁴ and the total annual cost for providing a toll-free number will be \$36,240.

In sum, the total estimate for non-labor costs is \$49,960: \$7,920 (services of a forensic expert) + \$5,800 (costs of notifying consumers) + \$36,240 (cost of providing a toll-free number).

The total estimated PRA annual cost burden is \$61,764 (labor costs) + \$49,960 (non-labor costs) = approximately \$112,000 (rounded to the nearest thousand).

Request for Comments

You can file a comment online or on paper. Write "Health Breach Notification Rule, PRA Comments, P-125402" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics,

¹³ According to industry research, the cost of a single T1 line is \$1,500 per month.

¹⁴ Staff estimates a monthly charge of \$15 along with an activation charge of \$15 for each toll-free line, as well as a per minute charge of \$.07. Since staff estimates each breach will require 1067 hours of telephone operator time (see note 10, *infra*), staff estimates the cost/month of each toll-free line to be \$4,540.

inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/healthbreachnotificationpra> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov>, you also may file a comment through that Web site.

If you file your comment on paper, write "Health Breach Notification Rule, PRA Comments, P-125402" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610, (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610, (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 15, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2015-26362 Filed 10-15-15; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ).

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Tuesday, November 3, 2015, from 8:30 a.m. to 2:45 p.m.

ADDRESSES: The meeting will be held at the Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850, (301) 427-1456. For press-related information, please contact Alison Hunt at (301) 427-1244.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Friday, October 23, 2015. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850. Ms. Campbell's phone number is (301) 427-1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of

the Agency in light of private sector activity and opportunities for public private partnerships.

The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Tuesday, November 3, 2015, there will be a subcommittee meeting for the National Healthcare Quality and Disparities Report scheduled to begin at 7:30 a.m. The subcommittee meeting is open to the public. The Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at www.webconferences.com/ahrq. The meeting will begin with the AHRQ director presenting an update on current research, programs, and initiatives. Following the Director's update, the agenda will include discussion of AHRQ's work on health information technology (Health IT), a presentation on the Medical Expenditure Panel Survey (MEPS), and discussion on the recent IOM report on diagnostic errors. The final agenda will be available on the AHRQ Web site at www.AHRQ.gov no later than Friday, October 23, 2015.

Sharon B. Arnold,
Deputy.

[FR Doc. 2015-26319 Filed 10-15-15; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR-2015-0002]

Availability of Draft Toxicological Profile; Set 27 Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for comment.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), located within the Department of Health and Human Services (HHS) announces the availability of Set 27 Toxicological Profiles for review and comment. The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by

the Superfund Amendments and Reauthorization Act of 1986 (SARA), § 104(i)(3), (42 U.S.C. 9604(i)(3)), directs the ATSDR Administrator to prepare Toxicological Profiles of Priority hazardous substances and, as necessary, to revise and publish each updated toxicological profile.

Comments can include additional information or reports on studies about the health effects of Set 27 substances. Although ATSDR considered key studies for each of these substances during the profile development process, the **Federal Register** notice solicits any relevant, additional studies, particularly unpublished data. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion into the profile. ATSDR remains committed to providing a public comment period for this document as a means to best serve public health and our clients.

DATES: Written comments on this draft Toxicological Profile must be received on or before January 14, 2016.

ADDRESSES: You may submit comments, identified by docket number ATSDR-2015-0002, by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.
- *Mail:* Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE., MS F-57, Atlanta, GA 30329. Attn: Docket No. ATSDR-2015-0002.

Instructions: All submissions received must include the agency name and docket number for this notice. All relevant comments will be posted without change. Because all public comments regarding ATSDR Toxicological Profiles are available for public inspection, no confidential business information or other confidential information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Delores Grant, Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE., MS F-57, Atlanta, GA 30329. Phone: (800) 232-4636 or 770-488-3351.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99-499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain responsibilities for ATSDR and the U.S. Environmental Protection Agency (U.S. EPA) regarding hazardous substances

most commonly found at facilities on the CERCLA National Priorities List (NPL). As part of these responsibilities, the ATSDR Administrator must prepare Toxicological Profiles for substances enumerated on the priority list of hazardous substances. This list identifies 275 hazardous substances which, according to ATSDR and U.S. EPA, pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on May 28, 2014 (79 FR 30613). In addition, ATSDR has the authority to prepare Toxicological Profiles for substances not found at sites on the National Priorities List, in an effort to “. . . establish and maintain inventory of literature, research, and studies on the health effects of toxic substances” under CERCLA Section 104(i)(1)(B). ATSDR also prepares Toxicological Profiles in response to requests for consultation under section 104(i)(4), and as otherwise necessary to support the site-specific response actions conducted by ATSDR.

Each profile will include an examination, a summary, and an interpretation of available toxicological information and epidemiological evaluations. This information and these data identify the levels of significant human exposure for the substance and for the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available (or in the process of development) in order to identify levels of significant human exposure. If adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to ensure the initiation of a program of research to provide such information.

SET 27 TOXICOLOGICAL PROFILES

	Name
1 ..	Polybrominated Biphenyl Ethers (PBDEs) UPDATE.
2 ..	N,N-Diethyl-meta-toluamide (DEET).
3 ..	Toluene Diisocyanates (mixture). Methylenediphenyl Diisocyanates (NEW).
4 ..	Nitrates/Nitrites (NEW).
5 ..	Toluene (UPDATE).

The Set 27 Toxicological Profiles are available online at <http://www.atsdr.cdc.gov/toxprofiles/index.asp> and <http://www.regulations.gov>.

www.regulations.gov, Docket No. ATSDR-2015-0002.

Donna B. Knutson,

Acting Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry.

[FR Doc. 2015-26321 Filed 10-15-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10003, CMS-10467, CMS-1450(UB-04), CMS-1500(08-05)]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *December 15, 2015*.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the

instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development,
Attention: Document Identifier/OMB
Control Number _____,
Room C4–26–05,
7500 Security Boulevard,
Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT:
Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS–10003 Notice of Denial of Medical Coverage (or Payment)

CMS–10467 Evaluation of the Graduate Nurse Education Demonstration Program

CMS–1450(UB–04) Medicare Uniform Institutional Provider Bill and Supporting Regulations CMS–1500(08–05) Health Insurance Common Claims Form and Supporting Regulations

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a

60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection*

Request: Revision of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medical Coverage (or Payment); *Use:* Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans, are required to issue the CMS–10003 form when a request for either a medical service or payment is denied in whole or in part. The notice explains why the plan denied the service or payment and informs Medicare enrollees of their appeal rights. The notice is also used, as appropriate, to explain Medicaid appeal rights to full dual eligible individuals enrolled in a Medicare health plan that is also managing the individual’s Medicaid benefits. To that end, the revised notice contains bracketed text the plan will insert if the denial notice is being delivered to an enrollee who is a full dual eligible. The text in square brackets “[]” reflects the Federal protections for Medicaid managed care enrollees. Since a State may offer additional protections, there is also free-text space for inclusion of any State-specific protections that exceed the Federal protections. *Form Number:* CMS–10003 (OMB control number: 0938–0829). *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 33,574,293; *Total Annual Hours:* 5,593,477. (For policy questions regarding this collection contact Staci Paige at 410–786–2045. For all other issues call 410–786–1326.)

2. *Type of Information Collection*

Request: Revision of a currently approved information collection; *Title of Information Collection:* Evaluation of the Graduate Nurse Education Demonstration Program; *Use:* The Graduate Nurse Education (GNE) Demonstration is mandated under Section 5509 of the Affordable Care Act (ACA) under title XVIII of the Social Security Act (42 U.S.C. 1395 *et seq.*). According to Section 5509 of the ACA, the five selected demonstration sites receive “payment for the hospital’s reasonable costs for the provision of qualified clinical training to advance

practice registered nurses.” Section 5509 of the ACA also states that an evaluation of the graduate nurse education demonstration must be completed no later than October 17, 2017. This evaluation includes analysis of the following: (1) Growth in the number of advanced practice registered nurses (APRNs) with respect to a specific base year as a result of the demonstration; (2) growth for each of the following specialties: clinical nurse specialist, nurse practitioner, certified nurse anesthetist, certified nurse-midwife; and (3) costs to the Medicare program as result of the demonstration.

All information collected through the Evaluation of the GNE project will be used to meet the requirements specified under the ACA Section 5509. We will also use the information to determine the overall effectiveness of the GNE project. The process evaluation seeks to understand how the demonstration is implemented overall, how that implementation has changed over time, which aspects of the demonstration have been successful or unsuccessful, and what plans the sites have for the remainder of the implementation and after the demonstration formally ends. The process evaluation will answer both quantitative and qualitative questions. *Form Number:* CMS–10467 (OMB control number: 0938–1212); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; Private sector (Business and other for-profit and Not-for-profit institutions); *Number of Respondents:* 104; *Total Annual Responses:* 104; *Total Annual Hours:* 802. (For policy questions regarding this collection contact Pauline Karikari-Martin at 410–786–1040.)

3. *Type of Information Collection*

Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; *Use:* Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Ninth Edition (ICD–9–CM) code. Inpatient procedures are identified by ICD–9–CM codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS). These are standard systems of identification for all major health insurance claims payers. Submission of information on the CMS–1450 permits Medicare intermediaries to receive consistent data for proper payment. *Form Numbers:* CMS–1450 (UB–04)

(OMB control number: 0938-0997); *Frequency*: On occasion; *Affected Public*: Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents*: 53,111; *Total Annual Responses*: 181,909,654; *Total Annual Hours*: 1,567,455. (For policy questions regarding this collection contact Matt Klischer at 410-786-7488.)

4. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection*: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, Subpart C; *Use*: The Form CMS-1500 answers the needs of many health insurers. It is the basic form prescribed by CMS for the Medicare program for claims from physicians and suppliers. The Medicaid State Agencies, CHAMPUS/TriCare, Blue Cross/Blue Shield Plans, the Federal Employees Health Benefit Plan, and several private health plans also use it; it is the de facto standard "professional" claim form.

Medicare carriers use the data collected on the CMS-1500 and the CMS-1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS-1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS-1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (e.g., CHAMPUS/TriCare, Railroad Retirement Board (RRB), and Medicaid). However, as the CMS-1500 displays data items required for other third-party payers in addition to Medicare, the form is considered too complex for use by beneficiaries when they file their own claims. Therefore,

the CMS-1490S (Patient's Request for Medicare Payment) was explicitly developed for easy use by beneficiaries who file their own claims. The form can be obtained from any Social Security office or Medicare carrier. *Form Number*: CMS-1500(08/05), CMS-1490-S (OMB control number: 0938-0999) *Frequency*: On occasion; *Affected Public*: State, Local, or Tribal Governments, Private sector (Business or other-for-profit and Not-for-profit institutions); *Number of Respondents*: 1,448,346; *Total Annual Responses*: 988,005,045; *Total Annual Hours*: 21,418,336. (For policy questions regarding this collection contact Shannon Seales at 410-786-4089.)

Dated: October 13, 2015.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-26390 Filed 10-15-15; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Native Language Preservation and Maintenance Grant Application Template Pilot (Funding Application Submission Tool (F.A.S.T. form))

OMB No.:
Description: The proposed F.A.S.T. form is intended to be used by applicants in the Administration for Native Americans' Native American Language Preservation and Maintenance grant competition in FY 2016. The F.A.S.T. form is proposed to be piloted as a consolidated and streamlined pre-

formatted electronic application form that is user-friendly and has an interactive interface providing structure and clarity for applicants. The proposed F.A.S.T. form is not intended to replace the Funding Opportunity Announcement (FOAs) which will still function as the full text of all funding opportunities for which applications are sought and considered by the Administration for Native Americans.

The proposed F.A.S.T. form will be used in a pilot capacity in just one Administration for Native Americans' discretionary program areas: Native American Language Preservation and Maintenance. All applicants applying for funding in that program area will be required to use the F.A.S.T. form during the pilot competition proposed for FY16 unless they request and receive approval to submit a paper application. By using the F.A.S.T. form no applicant will be required to provide any information beyond what is already required by the FOA. Additionally, free training and technical assistance will be available to all applicants on use of the F.A.S.T. form.

ANA intends to use the project proposals submitted via the F.A.S.T. form to make funding decisions for Native American Language Preservation and Maintenance grant awards made in the FY 2016 pilot year. In addition, ANA will solicit feedback from applicants and panel reviewers to obtain feedback on the results, outcomes, and their recommendations regarding the F.A.S.T. form as a user friendly method of applying for funding opportunities. If the pilot is successful in making it easier for applicants to apply, ANA will consider potentially expanding use of the F.A.S.T. form to all Administration for Native Americans' discretionary funding areas in subsequent years.

Respondents: 40.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
F.A.S.T. form	40	28	.50	14

Estimated Total Annual Burden Hours: 560.

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, Email: OIRA_SUBMISSION@OMB.EOP.GOV,

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015-26320 Filed 10-15-15; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3474]

Draft Recommendations for the Permitted Daily Exposures for Two Solvents, Triethylamine and Methylisobutylketone, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Conference on Harmonisation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft recommendations for a new permitted daily exposure (PDE) for the residual solvent triethylamine and a revised PDE for the residual solvent methylisobutylketone, according to the maintenance procedures for the guidance for industry entitled “Q3C Impurities: Residual Solvents.” The draft recommendations were prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of the patient.

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 the draft recommendations before it begins work on the final recommendations, submit either electronic or written comments on the document by December 15, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [http://](http://www.regulations.gov)

www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2015-D-3474 for “Draft Recommendations for the Permitted Daily Exposures for Two Solvents, Triethylamine and Methylisobutylketone, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Conference on Harmonisation; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft recommendations to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft recommendations may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendations.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Timothy J. McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6300, Silver Spring, MD 20993-0002, 240-402-0477.

Regarding the ICH: Michelle Limoli, CBER International Programs, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7212, Silver Spring, MD 20993-0002, 301-796-8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: Europe, Japan, and North America. The eight ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; and Swissmedic. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization.

In the **Federal Register** of December 24, 1997 (62 FR 67377), FDA published the ICH guidance for industry entitled "Q3C Impurities: Residual Solvents." The guidance makes recommendations as to what amounts of residual solvents are considered to be toxicologically acceptable for some residual solvents. Upon issuance in 1997, the text and appendix 1 of the guidance contained several tables and a list of solvents categorizing residual solvents by toxicity, classes 1 through 3, with class 1 being the most toxic. The ICH Quality Expert Working Group (EWG) agreed that the PDE could be modified if

reliable and more relevant toxicity data were brought to the attention of the group and the modified PDE could result in a revision of the tables and list.

In 1999, ICH instituted a Q3C maintenance agreement and formed a maintenance EWG (Q3C EWG). The agreement provided for the revisitation of solvent PDEs and allowed for minor changes to the tables and list that include the existing PDEs. The agreement also provided that new solvents and PDEs could be added to the tables and list based on adequate toxicity data. In the **Federal Register** of February 12, 2002 (67 FR 6542), FDA briefly described the process for proposing future revisions to the PDE. In the same notice, the Agency announced its decision to delink the tables and list from the Q3C guidance and create a stand-alone document entitled "Q3C: Tables and List" to facilitate making changes recommended by ICH.

In June 2015, the ICH Steering Committee agreed that draft recommendations for a new PDE for the residual solvent triethylamine and a revised PDE for the residual solvent methylisobutylketone should be made available for public comment. The draft recommendations are the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft recommendations provide guidance on the new PDE for the solvent trimethylamine and the revised PDE for the solvent methylisobutylketone. In addition, the data used to derive the PDEs are summarized. The document is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of the patient.

The draft recommendations are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft recommendations for the solvents trimethylamine and methylisobutylketone, when finalized, will represent the current thinking of FDA on this topic. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/>

BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Dated: October 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-26361 Filed 10-15-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3403]

Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: Under the auspices of the National Science and Technology Council, the Food and Drug Administration (FDA or the Agency), along with the Office of Science and Technology Policy (OSTP), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA), is announcing a public meeting, to be held on October 30, 2015, to discuss the memorandum entitled, "Modernizing the Regulatory System for Biotechnology Products," issued by the Executive Office of the President (EOP) in July 2015. The purpose of the meeting is to inform the public about the activities described in the July 2015 memorandum; invite oral comments from interested parties; and provide information about how to submit written comments, data, or other information to the docket.

DATES: See section II, "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document for the date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management. Comments may be submitted in writing until November 13, 2015.

ADDRESSES: See section II, "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-N-3403 for "Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting." Comments received will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: For general questions about the meeting, to request an opportunity to make an oral presentation at the public meeting, to submit the full text or summary of an oral presentation, or for special accommodations due to a disability, contact the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830, email: BiotechnologyUpdate@fda.hhs.gov.

For questions about the memorandum entitled, "Modernizing the Regulatory System for Biotechnology Products," or related activities described in that memorandum, contact the National Science and Technology Council: Emerging Technologies Interagency

Policy Coordination Committee, Office of Science and Technology Policy, Executive Office of the President, Eisenhower Executive Office Building, 1650 Pennsylvania Ave., Washington DC 20504, 202-456-4444, online: <https://www.whitehouse.gov/webform/contact-emerging-technologies-interagency-policy-coordinating-committee-national-science-and->

SUPPLEMENTARY INFORMATION:

I. Background

In 1986, OSTP issued the Coordinated Framework for Regulation of Biotechnology (CF), which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation (51 FR 23302; June 26, 1986) (Ref. 1).

In 1992, OSTP issued an update to the CF that set forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment (57 FR 6753; February 27, 1992) (Ref. 2). The update affirmed that Federal oversight should focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created.

On July 2, 2015, the EOP issued a memorandum entitled, "Modernizing the Regulatory System for Biotechnology Products," (the EOP memorandum) directing the primary federal Agencies that have oversight responsibilities for the products of biotechnology—EPA, FDA, and USDA—to update the CF to clarify current roles and responsibilities of the Agencies that regulate the products of biotechnology, develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology, and commission an independent, expert analysis of the future landscape of biotechnology products (Ref. 3). These efforts will build on the regulatory principles described in the CF and the 1992 update to the CF. The EOP memorandum's objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

The July 2, 2015, EOP memorandum stated that the update to the CF should clarify the current roles and responsibilities of the Agencies that regulate the products of biotechnology by accomplishing the following four objectives:

1. Clarifying which biotechnology product areas are within the authority and responsibility of each Agency.
2. Clarifying the roles that each Agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment.

3. Clarifying a standard mechanism for communication and, as appropriate, coordination among Agencies, while they perform their respective regulatory functions, and for identifying Agency designees responsible for this coordination function.

4. Clarifying the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment, and promote the public trust in the regulatory systems for biotechnology products.

As noted in the EOP memorandum, “biotechnology products” refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in the EOP memorandum.

In addition, on October 6, 2015, OSTP issued a notice of request for information (RFI) to solicit data and information, including case studies, that can inform the development of the proposed update to the CF and the development of a long-term strategy

consistent with the objectives described in the July 2, 2015, EOP memorandum (80 FR 60414). In addition to the RFI, the EOP noted that it will hold three public engagement sessions over the next 12 months (Ref. 4), and that the current update to the CF will undergo public notice and comment before it is finalized. This notice is announcing the first public engagement session.

The purpose of this first public meeting is to inform the public about the activities described in the EOP memorandum; invite oral, stakeholder comments relevant to those activities; and provide information about how to submit written comments, data, or other information to the docket. At this public meeting, OSTP will provide an overview of the CF and the 1992 update to the CF, and discuss the activities described in the EOP memorandum. EPA, FDA, and USDA will provide an overview of their current approaches to regulating products of biotechnology. The agenda for this public meeting will be posted approximately 5 days before the meeting at: <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm463783.htm>.

II. How To Participate in the Public Meeting

OSTP, EPA, FDA, and USDA (collectively referred to as “we” or “us”) are holding the public meeting under the auspices of the National Science and Technology Council. The meeting will be held on October 30, 2015, in the White Oak Great Room, at FDA’s White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503 B&C), 10903 New Hampshire Ave., Silver Spring, MD 20993–002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/>

[ucm241740.htm](#). Due to limited space and time, we encourage all persons who wish to attend the meeting to register early and in advance of the meeting. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request in advance and to provide information about any specific topic or issue to be addressed. There will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. We would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

We encourage persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, we will notify each participant before the meeting of the approximate start time of their presentation and of the amount of time allotted for the comment.

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, interested parties may submit electronic or written comments to the docket. All relevant data and documentation should be submitted with the comments to Docket No. FDA–2015–N–3403.

Table 1 provides information on participation in the public meeting.

TABLE 1—INFORMATION ON PARTICIPATION IN THE PUBLIC MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET

	Date	Electronic address	Address	Other information
Public meeting	October 30, 2015	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	FDA’s White Oak Campus, Building 31 Conference Center, the Great Room (1503–B&C), 10903 New Hampshire Ave., Silver Spring, MD 20993–002.	
Deadline for registration.	October 21, 2015	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm . Docket No. FDA–2015–N–3403.	We encourage you to use electronic registration if possible ¹ .	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.

TABLE 1—INFORMATION ON PARTICIPATION IN THE PUBLIC MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET—
Continued

	Date	Electronic address	Address	Other information
Request to make a public comment.	October 21, 2015	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Request special accommodations due to a disability.	October 21, 2015	Email: BiotechnologyUpdate@fda.hhs.gov .	Office of Policy, Office of the Commissioner, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830.	
Closing date for written comments.	November 13, 2015 ..	http://www.regulations.gov	See ADDRESSES above.	

¹ For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX or email, contact: Office of Policy, Office of the Commissioner, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830, email: BiotechnologyUpdate@fda.hhs.gov.

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to us will become part of the administrative record for this activity, and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record for this activity. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and on FDA's Web site at: <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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, 5630 Fishers Lane, Rm. 1035, Rockville, MD 20857. Additionally, we will live webcast and record the public meeting. Once the recorded video is available, it will be accessible on FDA's Web site at: <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are

also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Executive Office of the President. Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 FR 23302, June 26, 1986. Available online at: http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.
2. Executive Office of the President. Office of Science and Technology Policy. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment. 57 FR 6753, February 27, 1992. Available online at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753_1992.pdf.
3. Executive Office of the President. Office of Science and Technology Policy, Office of Management and Budget, United States Trade Representative, and Council on Environmental Quality. Modernizing the Regulatory System for Biotechnology Products, July 2, 2015. Available online at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.
4. Executive Office of the President. Improving Transparency and Ensuring Continued Safety in Biotechnology, blog post, July 2, 2015. Available online at: <https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology>.

Dated: October 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-26311 Filed 10-15-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; Media-Smart Youth Leaders Program (NICHHD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), will issue a funding announcement for the Media-Smart Youth Leaders Program to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: Whether the proposed collection of information is necessary for the proper selection of facilitators to serve as local health educators, using the Media-Smart Youth curriculum; the accuracy of the agency's estimate of the burden of the proposed 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sarah Glavin, Acting Director, Office of Science Policy, Analysis, and Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Dr., Bldg. 31, Rm. 2A28, Bethesda, MD 20892, or call non-toll-free number (301) 496-7898, or email your request, including your address to: glavins@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 60 days of the date of this publication.

Proposed Collection: Application for Consideration for the Media-Smart Youth Leaders Program (A Local Health Education Program and Leadership Opportunity): 0925—New, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: Media-Smart Youth: Eat, Think, and Be Active!® is an interactive program designed to teach youth ages 11–13 about how media can affect their health. Developed by the NIH’s Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the program includes 10 lessons on media analysis, nutrition, and physical activity, plus a final capstone project. The Media-Smart Youth® Leaders Program is designed for teens and adults, ages 15 years and up, who are interested in bringing the Media-Smart Youth program to their community. In return for recruiting youth participants, teaching the 10

lessons, and leading the final project, Media-Smart Youth Leaders will receive leadership experience, community service hours, and recognition from the NICHD. To help Leaders succeed, the NICHD will provide training, ongoing assistance, and a small funding amount for program expenses.

The purpose of this information collection is to solicit information from applicants about their qualifications that would make them effective Leaders, their reason for wanting to pursue this opportunity, and the details of their proposed program (including, but not limited to, location, community partner(s), and proposed budget). This information will help NICHD staff select the candidates for the program who are most likely to succeed in implementing the full curriculum and teaching youth effective lessons about nutrition, physical activity, and media.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 800.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Media-Smart Youth Leaders Program Application Form.	Applicants	300	1	2.5	750
Media-Smart Youth Leaders Program Application Form.	Advisors	300	1	5/60	25
Media-Smart Youth Leaders Program Application Form.	Community partners	300	1	5/60	25

Dated: October 10, 2015.

Sarah Glavin,

Project Clearance Liaison, NICHD, NIH.

[FR Doc. 2015-26389 Filed 10-15-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke, Interagency Pain Research Coordinating Committee Call for Committee Membership Nominations

SUMMARY: The Department of Health and Human Services (HHS) (Department) has created the Interagency Pain Research Coordinating Committee and is seeking nominations for this committee.

DATES: Nominations are due by 5 p.m. on November 19, 2015.

ADDRESSES: Nominations must be submitted through the web form on the IPRCC Web site: <http://iprcc.nih.gov/about/IPRCC-Nomination.htm>.

FOR FURTHER INFORMATION CONTACT: Linda Porter, porterl@ninds.nih.gov.

SUPPLEMENTARY INFORMATION: As specified in Public Law 111-148 (“Patient Protection and Affordable Care Act”) the Committee will: (a) Develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain; (b) identify critical gaps in basic and clinical research on the symptoms and causes of pain; (c) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(d) make recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

Membership on the committee will include six (6) non-Federal members from among scientists, physicians, and other health professionals and six (6) non-Federal members of the general public who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. Members will serve overlapping three year terms. It is anticipated that the committee will meet at least once a year.

The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee’s function. Every effort is made to ensure that the views of diverse ethnic and racial groups and

people with disabilities are represented on HHS Federal advisory committees, and the Department therefore, encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Department is soliciting nominations for two non-federal members from among scientists, physicians, and other health professionals and for one non-federal member of the general public who is a representative of a leading research, advocacy, or service organization for people with pain-related conditions. These candidates will be considered to fill positions opened through completion of current member terms. Nominations are due by 5 p.m. on November 19, 2015, using the IPRCC nomination web form: <http://iprcc.nih.gov/about/IPRCC-Nomination.htm>.

Dated: October 8, 2015.

Walter J. Koroshetz,

Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

[FR Doc. 2015-26408 Filed 10-15-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notice of proposed changes to the *NIH Guidelines*.

SUMMARY: The NIH seeks public comment on its proposal to amend the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to incorporate the recommendations of the Institute of Medicine (IOM) regarding human gene transfer clinical research protocols. The NIH proposes amendments to the following: (A) The criteria for selecting protocols for in-depth review and public discussion by the NIH Recombinant DNA Advisory Committee (RAC), (B) the process by which human gene transfer protocols

are reviewed and registered with the NIH, and (C) the streamlining of the NIH protocol registration submission requirements under Appendix M-I-A of the *NIH Guidelines*.

DATES: To ensure consideration, comments must be submitted in writing by November 30, 2015.

ADDRESSES: Comments may be submitted by email at OBA-osp@od.nih.gov, by fax at 301-496-9839, or by mail to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985. All written comments received in response to this notice will be available for public inspection at the NIH Office of Science Policy (OSP), 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted to the NIH OSP Web site.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional background information about these proposed changes, please contact the NIH by email at OBA-osp@od.nih.gov, or telephone at 301-496-9838.

SUPPLEMENTARY INFORMATION: The NIH Office of the Director requested that the IOM review whether gene transfer research raises issues of concern that warrant the current level of RAC oversight of individual clinical trials involving gene transfer techniques. The IOM noted that the RAC has served a valuable role, but concluded that the current level of oversight over individual clinical trials is no longer justifiable. In an effort to maximize the benefits of the RAC review process, the IOM recommended that the NIH maintain its protocol submission and safety reporting requirements, but restrict individual gene transfer protocol reviews to exceptional cases that meet specified criteria (full recommendations are listed in the IOM report *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee* (<http://www.iom.edu/Reports/2013/Oversight-and-Review-of-Clinical-Gen-Transfer-Protocols.aspx>)).

After careful consideration of the IOM's recommendations, the NIH proposes amendments to the *NIH Guidelines* in the following areas:

A. *Criteria and process for selecting protocols for RAC review.* The following criteria (subsequently referred to as the NIH RAC review criteria) are proposed for initiating RAC review of individual human gene transfer protocols (criteria listed in both items 1 and 2 must be met):

1. An oversight body (an Institutional Biosafety Committee (IBC) or an Institutional Review Board (IRB)) determines that a human gene transfer protocol submitted to it for approval would significantly benefit from RAC review; and

2. One or more of the criteria below are satisfied:

a. The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk.

b. The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value.

c. The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously.

The chair of an oversight body or an authorized oversight body representative may submit a request for RAC review by sending the request to the NIH as part of the submission materials provided by the PI. This request must include the rationale for why the protocol satisfies both items 1 and 2 of the NIH RAC review criteria. The NIH will review the request and notify the requestor of a decision in no more than ten working days.

1. If the NIH determines that the criteria listed in both 1 and 2 above are satisfied, the NIH Director will convene the RAC.

2. If the NIH receives a request for RAC review of a protocol that the NIH determines does not meet both of these criteria, the NIH would:

a. Inform the requestor that RAC review is not warranted, and

b. offer to provide the requestor with information about previous protocols that have used similar products, the outcome of those studies, if available, and a summary of relevant safety data.

3. Even if the protocol does not meet the proposed criteria listed in both items 1 and 2 above, the NIH Director, in consultation (if necessary) with appropriate regulatory authorities (e.g., the Office for Human Research Protections, the Food and Drug Administration), can select protocols for review that may present significant scientific, societal, or ethical concerns.

B. *Process by which human gene transfer protocols are registered with the NIH.* All human gene transfer protocols subject to Section III-C of the *NIH Guidelines* will continue to be registered with the NIH. However, the following changes are being proposed:

1. The Principal Investigator (PI) will continue to be responsible for submitting documentation regarding a proposed human gene transfer protocol to his or her local oversight bodies. The PI will also continue to be responsible for submitting documentation as outlined in Appendix M–I–A to the NIH. As part of the submission to the NIH, the PI shall provide documentation from oversight bodies regarding their assessment of whether RAC review is warranted.

2. Completion of the protocol registration process:

a. If no oversight body requests RAC review, the IBC may proceed with its approval process upon receipt of documentation from the NIH indicating that the protocol registration process is complete. No research participant shall be enrolled (see definition of enrollment in Section I–E–7) in the human gene transfer protocol until the protocol registration process has been completed.

b. If an oversight body requests review and the NIH agrees that the submission has met the criteria in A above, the protocol will undergo RAC review and public discussion. The IBC may not approve a protocol until the RAC review process has been completed. The IBC may proceed with its approval process upon receipt of documentation from the NIH indicating that the protocol registration process is complete. No research participant shall be enrolled (see definition of enrollment in Section I–E–7) in the human gene transfer protocol until the protocol registration process has been completed.

c. *Streamlining the submission requirements for protocol registration.* Section III–C–1 and Appendix M of the *NIH Guidelines* specify the requirements for protocol submission, RAC review, and reporting requirements for human gene transfer experiments. In an effort to streamline the protocol submission process, the NIH proposes to reduce the submission requirements as outlined in Appendix M–I–A. Specifically, only a subset of the information listed under the current Appendices M–II through M–V will be required mainly for oversight bodies to determine RAC review eligibility and to support the Genetic Modification Clinical Research Information System (GeMCRIS[®]), which facilitates safety reporting and provides access to information about human gene transfer protocols registered with the NIH.

The proposed changes to the RAC review process, outlined above, will require amendment of multiple portions of the *NIH Guidelines*.

Proposed Amendments to the NIH Guidelines

Throughout the document the following global changes will be made: (i) The NIH OSP will replace the NIH OBA, (ii) the term “RAC review” will be replaced with the term “NIH protocol registration process” as appropriate; (iii) the title for Appendix M–I–B will be changed; and (iv) the requirement for a CV/biosketch of key personnel will be deleted.

Section I–E is proposed to be amended to include the following new definitions:

I–E–11. An “oversight body” is an institutional entity (an Institutional Biosafety Committee or an Institutional Review Board) that must review and approve a human gene transfer trial.

I–E–12. A “regulatory authority” is a federal entity that by statute has oversight over research involving humans.

Section III–C–1 currently states:

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived From Recombinant or Synthetic Nucleic Acid Molecules, Into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules that meet any one of the following criteria:
 - a. Contain more than 100 nucleotides; or
 - b. Possess biological properties that enable integration into the genome (*e.g.*, *cis* elements involved in integration); or
 - c. Have the potential to replicate in a cell; or
 - d. Can be translated or transcribed.

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) until the RAC review process has been completed (see Appendix M–I–B, RAC Review Requirements).

In its evaluation of human gene transfer proposals, the RAC will consider whether a proposed human gene transfer experiment presents characteristics that warrant public RAC review and discussion (See Appendix M–I–B–2). The process of public RAC review and discussion is intended to foster the safe and ethical conduct of human gene transfer experiments. Public review and discussion of a human gene transfer experiment (and access to relevant information) also serves to inform the public about the technical aspects of the proposal, the meaning and significance of the research, and any significant safety, social, and ethical implications of the research.

Public RAC review and discussion of a human gene transfer experiment may be: (1)

Initiated by the NIH Director; or (2) initiated by the NIH OBA Director following a recommendation to NIH OBA by: (a) Three or more RAC members; or (b) a Federal agency other than NIH. After a human gene transfer experiment is reviewed by the RAC at a regularly scheduled meeting, NIH OBA will send a letter, unless NIH OBA determines that there are exceptional circumstances, within 10 working days to the NIH Director, the Principal Investigator, the sponsoring institution, and other DHHS components, as appropriate, summarizing the RAC recommendations.

For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled (see definition of enrollment in Section I–E–7) at the clinical trial site until the following documentation has been submitted to NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

In order to maintain public access to information regarding human gene transfer (including protocols that are not publicly reviewed by the RAC), NIH OBA will maintain the documentation described in Appendices M–I through M–V. The information provided in response to Appendix M should not contain any confidential commercial information or trade secrets, enabling all aspects of RAC review to be open to the public.

Note: For specific directives concerning the use of retroviral vectors for gene delivery, consult Appendix B–V–1, Murine, Retroviral Vectors.

Section III–C–1 is proposed to be amended as follows:

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived From Recombinant or Synthetic Nucleic Acid Molecules, Into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules that meet any one of the following criteria:
 - a. Contain more than 100 nucleotides; or
 - b. Possess biological properties that enable integration into the genome (*e.g.*, *cis* elements involved in integration); or
 - c. Have the potential to replicate in a cell; or
 - d. Can be translated or transcribed.

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) until the NIH protocol registration process has been completed (see Appendix M–I–B, Selection of Individual Protocols for Public RAC Review and Discussion).

In its evaluation of human gene transfer protocols, the NIH will make a

determination, following a request from one or more oversight bodies, whether a proposed human gene transfer experiment has one or more of the characteristics that warrant public RAC review and discussion (See Appendix M-1-B-1). The process of public RAC review and discussion is intended to foster the safe and ethical conduct of human gene transfer experiments. Public review and discussion of a human gene transfer experiment (and access to relevant information) also serves to inform the public about the technical aspects of the proposal, the meaning and significance of the research, and any significant safety, social, and ethical implications of the research.

Public RAC review and discussion of a human gene transfer experiment may be initiated in two exceptional circumstances: (1) The NIH will determine, following a request for RAC public review from an oversight body, whether the protocol has one or more of the following characteristics: (i) The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; (ii) the protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or (iii) the proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously. If an oversight body requests public RAC review, but the protocol does not have one or more of the above characteristics (listed in i, ii, or iii), then the NIH will inform the requesting oversight body that public RAC review is not warranted. (2) Public RAC review and discussion of protocols not requested for review by an oversight body may be initiated by the NIH Director if: (a) The protocol has one or more of the three characteristics listed above (i, ii, or iii) and public RAC review and discussion would provide a clear and obvious benefit to the scientific community or the public; or (b) the protocol otherwise raises significant scientific, societal, or ethical concerns.

For a clinical trial site that is added after completion of the NIH protocol registration process, no research participant shall be enrolled (see definition of enrollment in Section I-E-7) at the clinical trial site until the following documentation has been submitted to the NIH OSP: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; and (4) the NIH grant number(s) if applicable.

In order to maintain public access to information regarding human gene transfer (including protocols that are not publicly reviewed by the RAC), the NIH OSP will maintain the documentation described in Appendices M-I through M-II. The information provided in response to Appendix M should not contain any confidential commercial or financial information or trade secrets, enabling all aspects of RAC review to be open to the public.

Note: For specific directives concerning the use of retroviral vectors for gene delivery,

consult Appendix B-V-1, Murine, Retroviral Vectors.

Section IV-B-1-f currently states:

Section IV-B-1-f. Ensure that when the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary), (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; and (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements). Institutional Biosafety Committee approval has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained. Institutional Biosafety Committee approval must be obtained from each institution at which recombinant or synthetic nucleic acids will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant or synthetic nucleic acid molecule material into target cells for human application).

Section IV-B-1-f is proposed to be amended as follows:

Section IV-B-1-f. Ensure that when the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary), (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; and (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M-I-B, Selection of Individual Protocols for Public RAC Review and Discussion), Institutional Biosafety Committee approval has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained. Institutional Biosafety Committee approval must be obtained from the clinical trial site.

None of the other sub-sections under Section IV-B-1. General Information are proposed to be amended.

Section IV-B-2-a-(1) currently states:

Section IV-B-2-a-(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members

shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (*e.g.*, officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals, require Institutional Biosafety Committee prior approval. When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B-3, Biological Safety Officer). When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary); (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements); and (iv) final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements). Institutional Biosafety Committee approval must be obtained from the institution at which recombinant or synthetic nucleic acid molecule material will be administered to human research participants (rather than the site involved in manufacturing gene transfer products).

Note: Individuals, corporations, and institutions not otherwise covered by the *NIH Guidelines*, are encouraged to adhere to the standards and procedures set forth in Sections I through IV (see Section IV-D, Voluntary Compliance). The policy and procedures for establishing an Institutional Biosafety Committee under Voluntary Compliance, are specified in Section IV-D-2, Institutional Biosafety Committee Approval).

Section IV-B-2-a-(1) is proposed to be amended as follows:

Section IV-B-2-a-(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals, require Institutional Biosafety Committee prior approval. When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B-3, Biological Safety Officer). When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that: (i) The Institutional Biosafety Committee has adequate expertise and training (using ad hoc consultants as deemed necessary); (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M-I-B, Selection of Individual Protocols for Public RAC Review and Discussion); and (iv) final IBC approval is granted only after the NIH protocol registration process has been completed (see Appendix M-I-B, Selection of Individual Protocols for Public RAC Review and Discussion). Institutional Biosafety Committee approval must be obtained from the clinical trial site.

Note: Individuals, corporations, and institutions not otherwise covered by the *NIH Guidelines*, are encouraged to adhere to the standards and procedures set forth in Sections I through IV (see Section IV-D, Voluntary Compliance). The policy and

procedures for establishing an Institutional Biosafety Committee under Voluntary Compliance, are specified in Section IV-D-2, Institutional Biosafety Committee Approval.

None of the other sub-sections under Section IV-B2-a. Membership and Procedures of the IBC are proposed to be amended.

Section IV-B-2-b-(1) currently states:

Section IV-B-2-b-(1). Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, Experiments Covered by the *NIH Guidelines*, and approving those research projects that are found to conform with the *NIH Guidelines*. This review shall include: (i) Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research; (iii) ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iv) ensuring that no research participant is enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements), Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained; (v) for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations; (vi) ensuring that final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements); and (vii) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.

Section IV-B-2-b-(1) is proposed to be amended as follows:

Section IV-B-2-b-(1). Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, Experiments Covered by the *NIH Guidelines*, and approving those research projects that are found to conform with the *NIH Guidelines*. This review shall include: (i) Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research; (iii) ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator (iv) ensuring that no research participant is enrolled (see definition of

enrollment in Section I-E-7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M-I-B, Selection of Individual Protocols for Public RAC Review and Discussion), Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained; (v) for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations; (vi) ensuring that final IBC approval is granted only after the NIH protocol registration process has been completed (see Appendix M-I-B, Selection of Individual Protocols for Public RAC Review and Discussion); and (vii) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.

None of the other sub-sections under Section IV-B-2-b. Functions of the IBC are proposed to be amended.

Section IV-B-6 currently states:

Section IV-B-6. Human Gene Therapy Expertise

When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using ad hoc consultants as deemed necessary) and (ii) all aspects of Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Subjects (Points to Consider), have been appropriately addressed by the Principal Investigator prior to submission to NIH/OBA.

Section IV-B-6 is proposed to be amended as follows:

Section IV-B-6. Human Gene Therapy Expertise

When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using ad hoc consultants as deemed necessary) and (ii) all aspects of Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Subjects (Points to Consider), have been appropriately addressed by the Principal Investigator prior to its approval.

Section IV-B-7-b-(6) currently states:

Section IV-B-7-b-(6). Ensure that all aspects of Appendix M have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA, and provide a letter signed by the Principal Investigator(s) on institutional

letterhead acknowledging that the documentation being submitted to NIH OBA complies with the requirements set forth in Appendix M. No research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements); IBC approval (from the clinical trial site) has been obtained; Institutional Review Board (IRB) approval has been obtained; and all applicable regulatory authorization(s) have been obtained.

For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled (see definition of enrollment in Section I-E-7) at the clinical trial site until the following documentation has been submitted to NIH OBA: (1) IBC approval (from the clinical trial site); (2) IRB approval; (3) IRB-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

Section IV-B-7-b-(6) is proposed to be amended as follows:

Section IV-B-7-b-(6). Ensure that all aspects of Appendix M have been appropriately addressed prior to submission. No research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M-I-B, Selection of Individual Protocols for Public RAC Review and Discussion); IBC approval (from the clinical trial site) has been obtained; Institutional Review Board (IRB) approval has been obtained; and all applicable regulatory authorization(s) have been obtained.

For a clinical trial site that is added after completion of the NIH protocol registration process, no research participant shall be enrolled (see definition of enrollment in Section I-E-7) at the clinical trial site until the following documentation has been submitted to the NIH OSP: (1) IBC approval (from the clinical trial site); (2) IRB approval; (3) IRB-approved informed consent document; and (4) NIH grant number(s) if applicable.

To implement this new process, the NIH proposes to amend Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Research Participants (Points to Consider).

Appendix M currently states:

Appendix M applies to research conducted at or sponsored by an institution that receives any support for recombinant or synthetic nucleic acid molecule research from NIH. Researchers not covered by the *NIH Guidelines* are encouraged to use Appendix M (see Section I-C, General Applicability).

The acceptability of human somatic cell gene transfer has been addressed in several public documents as well as in numerous

academic studies. In November 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published a report, *Splicing Life*, which resulted from a two-year process of public deliberation and hearings. Upon release of that report, a U.S. House of Representatives subcommittee held three days of public hearings with witnesses from a wide range of fields from the biomedical and social sciences to theology, philosophy, and law. In December 1984, the Office of Technology Assessment released a background paper, *Human Gene Therapy*, which concluded that civic, religious, scientific, and medical groups have all accepted, in principle, the appropriateness of gene transfer of somatic cells in humans for specific genetic diseases. Somatic cell gene transfer is seen as an extension of present methods that might be preferable to other technologies. In light of this public support, RAC is prepared to consider proposals for somatic cell gene transfer.

RAC will not at present entertain proposals for germ line alterations but will consider proposals involving somatic cell gene transfer. The purpose of somatic cell gene transfer is to treat an individual patient, *e.g.*, by inserting a properly functioning gene into the subject's somatic cells. Germ line alteration involves a specific attempt to introduce genetic changes into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring.

The RAC continues to explore the issues raised by the potential of *in utero* gene transfer clinical research. However, the RAC concludes that, at present, it is premature to undertake any *in utero* gene transfer clinical trial. Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human *in utero* gene transfer protocol can proceed. In addition, a more thorough understanding of the development of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human *in utero* gene transfer. Prerequisites for considering any specific human *in utero* gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the *in utero* approach. Once the above criteria are met, the RAC would be willing to consider well rationalized human *in utero* gene transfer clinical trials.

Research proposals involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from such nucleic acid molecules, into human subjects (human gene transfer) will be considered through a review process involving both NIH/OBA and RAC. Investigators shall submit their relevant information on the proposed human gene transfer experiments to NIH/OBA. Submission of human gene transfer protocols to NIH will be in the format described in Appendix M-I-A, Submission Requirements for Protocol Submission. Submission to NIH shall be for registration purposes and will

ensure continued public access to relevant human gene transfer information conducted in compliance with the *NIH Guidelines*. Investigational New Drug (IND) applications should be submitted to FDA in the format described in 21 CFR, Chapter I, Subchapter D, Part 312, Subpart B, Section 23, IND Content and Format.

Institutional Biosafety Committee approval must be obtained from each institution at which recombinant or synthetic nucleic acid molecule material will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant or synthetic nucleic acid molecule material into target cells for human application).

Factors that may contribute to public discussion of a human gene transfer experiment by RAC include: (i) New vectors/new gene delivery systems, (ii) new diseases, (iii) unique applications of gene transfer, and (iv) other issues considered to require further public discussion. Among the experiments that may be considered exempt from RAC discussion are those determined not to represent possible risk to human health or the environment. Full, public RAC review and discussion of a human gene transfer experiment may be (1) initiated by the NIH Director; or (2) initiated by the NIH OBA Director following a recommendation to NIH OBA by: (a) Three or more RAC members, or (b) a Federal agency other than NIH. An individual human gene transfer experiment that is recommended for full RAC review should represent novel characteristics deserving of public discussion. If it is determined that an experiment will undergo full RAC discussion, NIH/OBA will immediately notify the Principal Investigator. RAC members may forward individual requests for additional information relevant to a specific protocol through NIH/OBA to the Principal Investigator. In making a determination whether an experiment is novel, and thus deserving of full RAC discussion, reviewers will examine the scientific rationale, scientific context (relative to other proposals reviewed by RAC), whether the preliminary *in vitro* and *in vivo* safety data were obtained in appropriate models and are sufficient, and whether questions related to relevant social and ethical issues have been resolved. RAC recommendations on a specific human gene transfer experiment shall be forwarded to the NIH Director, the Principal Investigator, the sponsoring institution, and other DHHS components, as appropriate. Relevant documentation will be included in the material for the RAC meeting at which the experiment is scheduled to be discussed. RAC meetings will be open to the public except where trade secrets and proprietary information are reviewed (see Section IV-D-5, Protection of Proprietary Data—Voluntary Compliance). RAC prefers that information provided in response to Appendix M contain no proprietary data or trade secrets, enabling all aspects of the review to be open to the public.

Note: Any application submitted to NIH/OBA shall not be designated as 'confidential'

in its entirety. In the event that a sponsor determines that specific responses to one or more of the items described in Appendix M should be considered as proprietary or trade secret, each item should be clearly identified as such. The cover letter (attached to the submitted material) shall: (1) Clearly indicate that select portions of the application contain information considered as proprietary or trade secret, (2) a brief explanation as to the reason that each of these items is determined proprietary or trade secret.

Public discussion of human gene transfer experiments (and access to relevant information) shall serve to inform the public about the technical aspects of the proposals, meaning and significance of the research, and significant safety, social, and ethical implications of the research. RAC discussion is intended to ensure safe and ethical conduct of gene transfer experiments and facilitate public understanding of this novel area of biomedical research.

In its evaluation of human gene transfer proposals, RAC will consider whether the design of such experiments offers adequate assurance that their consequences will not go beyond their purpose, which is the same as the traditional purpose of clinical investigation, namely, to protect the health and well being of human subjects being treated while at the same time gathering generalizable knowledge. Two possible undesirable consequences of the transfer of recombinant or synthetic nucleic acid molecules would be unintentional: (i) Vertical transmission of genetic changes from an individual to his/her offspring, or (ii) horizontal transmission of viral infection to other persons with whom the individual comes in contact. Accordingly, Appendices M–I through M–V request information that will enable RAC and NIH/OBA to assess the possibility that the proposed experiment(s) will inadvertently affect reproductive cells or lead to infection of other people (e.g., medical personnel or relatives).

Appendix M will be considered for revisions as experience in evaluating proposals accumulates and as new scientific developments occur. This review will be carried out periodically as needed.

Appendix M is proposed to be amended as follows:

Appendix M applies to research conducted at or sponsored by an institution that receives any support for recombinant or synthetic nucleic acid molecule research from NIH. Researchers not covered by the *NIH Guidelines* are encouraged to use Appendix M (see Section I–C, General Applicability).

The acceptability of human somatic cell gene transfer has been addressed in several public documents as well as in numerous academic studies. In November 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published a report, *Splicing Life*, which resulted from a two-year process of public deliberation and hearings. Upon release of that report, a U.S. House of Representatives subcommittee held three days of public hearings with witnesses from a wide range of fields from the biomedical and social

sciences to theology, philosophy, and law. In December 1984, the Office of Technology Assessment released a background paper, *Human Gene Therapy*, which concluded that civic, religious, scientific, and medical groups have all accepted, in principle, the appropriateness of gene transfer of somatic cells in humans for specific genetic diseases. Somatic cell gene transfer is seen as an extension of present methods that might be preferable to other technologies. In light of this public support, the NIH is prepared to consider proposals for somatic cell gene transfer.

The NIH will not at present entertain proposals for germ line alterations but will consider proposals involving somatic cell gene transfer. The purpose of somatic cell gene transfer is to treat an individual patient, e.g., by inserting a properly functioning gene into the subject's somatic cells. Germ line alteration involves a specific attempt to introduce genetic changes into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring.

The NIH continues to explore the issues raised by the potential of *in utero* gene transfer clinical research. However, the NIH concludes that, at present, it is premature to undertake any *in utero* gene transfer clinical trial. Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human *in utero* gene transfer protocol can proceed. In addition, a more thorough understanding of the development of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human *in utero* gene transfer. Prerequisites for considering any specific human *in utero* gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the *in utero* approach. Once the above criteria are met, the NIH would be willing to consider well rationalized human *in utero* gene transfer clinical trials.

Research proposals involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from such nucleic acid molecules, into one or more human subjects (human gene transfer) will be considered through a registration process involving the NIH, oversight bodies, and regulatory authorities, when appropriate. Investigators shall submit the relevant information on the proposed human gene transfer experiment to the oversight bodies and then to the NIH. The format of the submission is described in Appendix M–I–A, Requirements for Protocol Submission. Submission to the NIH OSP shall be for registration purposes and will ensure continued public access to relevant human gene transfer information conducted in compliance with the *NIH Guidelines*.

Public RAC review and discussion of a human gene transfer experiment may be initiated in two exceptional circumstances: (1) The NIH will determine, following a request for RAC review from an oversight body, whether the protocol has one or more of the following characteristics: i) The

protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; ii) the protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or iii) the proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously. If an oversight body requests public RAC review, but the NIH determines that the protocol does not have one or more of the above characteristics (listed in i, ii, or iii), then the NIH will inform the requesting oversight body that public RAC review is not warranted. (2) Public RAC review and discussion of protocols not requested for review by an oversight body may be initiated by the NIH Director, after consultation (if needed) with appropriate regulatory authorities, if: (a) The protocol has one or more of the three characteristics listed above (i, ii, or iii) and public RAC review and discussion would provide a clear and obvious benefit to the scientific community or the public; or (b) the protocol otherwise raises significant scientific, societal, or ethical concerns.

If it is determined that a human gene transfer trial will undergo RAC review, the NIH will immediately notify the Principal Investigator. RAC recommendations following public review on a specific human gene transfer experiment shall be forwarded to the Principal Investigator, oversight bodies, and regulatory authorities, as appropriate. Relevant documentation will be included in the material for the RAC meeting at which the human gene transfer trial is scheduled to be discussed. RAC meetings will be open to the public except where trade secrets and proprietary information are reviewed (see Section IV–D–5, *Protection of Proprietary Data—Voluntary Compliance*). The NIH prefers that information provided in response to Appendix M contain no proprietary data or trade secrets, enabling all aspects of the review to be open to the public.

Some but not all sections of Appendix M–I Requirements for Protocol Submission, Review, and Reporting—Human Gene Transfer Experiments are proposed to be amended to decrease the number and amount of supporting documentation that must be submitted upon protocol registration, and to modify the timing of the registration processes. As proposed, Principal Investigators must submit the material as outlined below to oversight bodies at the proposed clinical trial sites; however, submission of responses to Appendices M–II through M–V or curriculum vitae will no longer be required.

Appendix M–I–A currently states: Appendix M–I.A. Requirements for Protocol Submission

The following documentation must be submitted (see exemption in Appendix M–III–A, Footnotes of Appendix M) in printed or electronic form to the: Office of Biotechnology Activities, National Institutes

of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax), Email: rosenthg@od.nih.gov. NIH OBA will confirm receipt within three working days after receiving the submission. Investigators should contact NIH OBA if they do not receive this confirmation.

1. A cover letter on institutional letterhead, signed by the Principal Investigator(s), that: (1) Acknowledges that the documentation submitted to NIH OBA complies with the requirements set forth in Appendix M-I-A, Requirements for Protocol Submission; (2) identifies the Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) at the proposed clinical trial site(s) responsible for local review and approval of the protocol; and (3) acknowledges that no research participant will be enrolled (see definition of enrollment in Section I-E-7) until the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements); IBC approval (from the clinical trial site) has been obtained; IRB approval has been obtained; and all applicable regulatory authorizations have been obtained.

2. The scientific abstract.

3. The non-technical abstract.

4. The proposed clinical protocol, including tables, figures, and relevant manuscripts.

5. Responses to Appendices M-II through M-V, Description of the Proposal, Informed Consent, Privacy, and Special Issues. Responses to Appendices M-II through M-V may be provided either as an appendix to the clinical protocol or incorporated in the clinical protocol. If responses to Appendices M-II through M-V are incorporated in the clinical protocol, each response must refer to the appropriate Appendix M-II through M-V.

6. The proposed informed consent document.

7. Curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format).

Note: A human gene transfer experiment submitted to NIH OBA should not contain confidential commercial information or trade secrets, enabling all aspects of the review to be open to the public.

Appendix M-I-A is proposed to be amended as follows:

Appendix M-I-A. Requirements for Protocol Submission

The following documentation must be submitted according to institutional policy, to the appropriate oversight bodies and subsequently in electronic form to the NIH OSP:

1. A scientific abstract.

2. The proposed clinical protocol, including tables, figures, and any relevant publications.

3. Summary of preclinical studies conducted in support of the proposed clinical trial or reference to the specific section of the protocol providing this information.

4. A description of the product:

a. Describe the derivation of the delivery vector system including the source (e.g.,

viral, bacterial, or plasmid vector); and modifications (e.g., deletions to attenuate or self-inactivate, encapsulation in any synthetic complex, changes to tropisms, etc.). Please reference any previous clinical experience with this vector or similar vectors.

b. Describe the genetic content of the transgene or nucleic acid delivered including the species source of the sequence and whether any modifications have been made (e.g. mutations, deletions, and truncations). What are the regulatory elements contained in the construct?

c. Describe any other material to be used in preparation of the agent (vector and transgene) that will be administered to the human research subject (e.g., helper virus, packaging cell line, carrier particles).

d. Describe the methods for replication-competent virus testing, if applicable.

e. Describe the intended *ex vivo* or *in vivo* target cells and transduction efficiency.

f. Describe the gene transfer agent delivery method.

5. The proposed informed consent document.

6. Specifically for submission to the NIH OSP, the PI shall provide additional documentation from oversight bodies regarding their assessment of whether RAC review is warranted. In the event that review is requested, the documentation shall include a justification that the protocol characteristics (see Section III-C-1) that would warrant RAC public review have been met.

Note: Any application submitted shall not contain any document that is designated as 'confidential' in its entirety. In the event that a sponsor determines that a portion of a specific document should be considered as proprietary or trade secret, each portion of the document should be clearly identified as such. In the event that a specific portion of the submission does contain information that a sponsor considers to be proprietary or trade secret, the submission to the NIH OSP must contain a letter from the sponsor that: (1) Clearly indicates what select portions of the application contain information considered as proprietary or trade secret, (2) provides an adequate and convincing justification as to the reason that this information is considered to be proprietary or trade secret. The justification must be able to demonstrate *with specificity* how release of that information will reveal a trade secret or will result in substantial competitive harm.

Appendix M-I-B, RAC Review Requirements is proposed to be amended to change the process and timing of initial and RAC review. Currently, investigators are informed within 15 working days whether or not the protocol requires public RAC review. Public discussion of selected protocols then occurs at the next quarterly RAC meeting, which occurs, at a minimum of, eight weeks after receipt of a complete protocol submission. Under the proposal, individual RAC members will no longer make a recommendation regarding whether a protocol should be selected for review at a public meeting.

Therefore, Appendix M-1-B-1 and Appendix M-1-B-2 are being amended

as follows to form a consolidated Appendix M-1-B:

Appendix M-1-B. Selection of Individual Protocols for Public RAC Review and Discussion

As part of the NIH protocol registration process, documentation from oversight bodies regarding their assessment of whether RAC review is warranted. If no oversight body would significantly benefit from public RAC review and discussion, then the Principal Investigator shall submit all of the documentation required to register the submission (see Appendix M-I-A) to the NIH OSP at any time but shall occur not less than three working days prior to the anticipated date of enrollment of the first subject (see definition of enrollment in Section I-E-7), and shall be provided in electronic form to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax), Email: HGTprotocols@mail.nih.gov. Enrollment may proceed upon acknowledgement that the submission is registered.

If an oversight body determines that: (1) A protocol submission would significantly benefit from public RAC review and discussion and (2) that one or more of the following NIH RAC review criteria are met: (i) The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; or (ii) the protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or (iii) the proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for local and federal regulatory bodies to evaluate the protocol rigorously, and is therefore requesting RAC review and public discussion, the Principal Investigator shall submit the documentation as outlined in Appendix M-I-A at least 8 weeks prior to the next scheduled meeting in order to be reviewed at that RAC meeting. The submission shall include documentation from oversight bodies regarding their assessment of whether RAC review is warranted and that one or both have justified their request according to the NIH RAC review criteria listed above. The submission shall be provided to the NIH in electronic form to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax), Email: HGTprotocols@mail.nih.gov. If NIH determines that any of the criteria listed in subsections (i), (ii), or (iii) above is met, the protocol will undergo public RAC review and discussion.

If an oversight body requests that the RAC review a protocol and the NIH determines that the protocol does not satisfy one or more of the above NIH RAC review criteria, the NIH OSP will inform the Principal Investigator, oversight bodies, and regulatory authorities, as appropriate, that RAC review is not warranted.

Even if an oversight body does not request that a particular protocol be reviewed by the RAC, the NIH Director, after consultation (if needed) with appropriate regulatory authorities, may initiate RAC review if (a) the protocol has one or more of the characteristics listed above (i, ii, or iii) and public RAC review and discussion would provide a clear and obvious benefit to the scientific community or public; or (b) the protocol otherwise raises significant scientific, societal, or ethical concerns.

Completion of the registration process is defined as: (1) Receipt by the Principal Investigator of a letter from the NIH OSP indicating that protocol registration process is complete and that enrollment may proceed; or (2) receipt by the Principal Investigator of a letter from the NIH after public RAC review that summarizes the committee's key comments and recommendations (if any).

A complete human gene transfer protocol package must be submitted at least eight weeks before a scheduled RAC meeting to be reviewed at that upcoming meeting.

After a human gene transfer experiment is publicly reviewed by the full RAC at a regularly scheduled meeting, the NIH OSP will send a letter summarizing the RAC's key comments and recommendations (if any) regarding the protocol to the Principal Investigator(s), oversight bodies, and regulatory authorities as appropriate. Completion of RAC review is defined as receipt by the Principal Investigator(s) of a letter from the NIH OSP summarizing the committee's findings. Unless the NIH determines that there are exceptional circumstances, the letter containing recommendations and comments made following public review will be sent within 10 working days after the completion of the RAC meeting at which the protocol was reviewed.

RAC meetings will be open to the public except where trade secrets or confidential commercial information are reviewed. To enable all aspects of the protocol review process to be open to the public, information provided in response to Appendix M-I-A should not contain trade secrets or confidential commercial or financial information. An application submitted to the NIH OSP shall not contain any document that is designated as 'confidential' in its entirety. In the event that a determination has been made that a specific portion of a document submitted as one of the items described in Appendix M should be considered as confidential commercial or financial information or a trade secret, each item must be clearly identified as such. The cover letter (attached to the submitted material) shall: (1) Clearly designate the information that is considered as confidential commercial or financial information or a trade secret; and (2) explain and justify each designation to demonstrate *with specificity* how release of that information will reveal a trade secret or will result in substantial competitive harm.

There are no proposed amendments to Appendix M-I-C, Reporting Requirements and Appendix M-I-D, Safety Assessments in Human Gene Transfer Research.

The current appendices Appendix M-II, Description of the Proposal; Appendix M-III, Informed Consent; Appendix M-IV, Privacy; and Appendix M-V, Special Issues are proposed to be deleted in their entirety, except for Appendix M-III-B-2-b, Long Term Follow-Up which will be updated to include a reference to FDA's current guidance on this issue and will become Appendix M-II.

Appendix M-II is proposed to be amended as follows:

Appendix M-II. Long Term Follow-Up

To permit evaluation of long-term safety and efficacy of gene transfer, prospective subjects should be informed that they are expected to cooperate in long-term follow-up that extends beyond the active phase of the study. A list of persons who can be contacted in the event that questions arise during the follow-up period should be provided to the investigator. In addition, the investigator should request that subjects continue to provide a current address and telephone number.

The subjects should be informed that any significant findings resulting from the study will be made known in a timely manner to them and/or their parent or guardian including new information about the experimental procedure, the harms and benefits experienced by other individuals involved in the study, and any long-term effects that have been observed.

Additional guidance is available in the FDA Guidance for Industry: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events (available at the following URL: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/default.htm>).

Appendix M-VI Footnotes of Appendix M will be renumbered to Appendix M-III. Footnotes of Appendix M. There will be no amendment to the language.

Dated: October 9, 2015.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2015-26388 Filed 10-15-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Environmental Health Sciences, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIEHS.

Date: November 15–17, 2015.

Closed: November 15, 2015, 7 p.m. to 10 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 16, 2015, 8:30 a.m. to 11:50 a.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 11:50 a.m. to 1:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: November 16, 2015, 1:30 p.m. to 3 p.m.

Agenda: Poster Session.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 3 p.m. to 3:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: November 16, 2015, 3:45 p.m. to 5:25 p.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 5:25 p.m. to 5:55 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 6:15 p.m. to 10 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 17, 2015, 8:30 a.m. to 10:10 a.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 17, 2015, 10:10 a.m. to 10:40 a.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: November 17, 2015, 10:55 a.m. to 12 p.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 17, 2015, 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Darryl C. Zeldin, Scientific Director & Principal Investigator, Division of Intramural Research, National Institute of Environmental Health Sciences, NIH, 111 TW Alexander Drive, Maildrop A2-09, Research Triangle Park, NC 27709, 919-541-1169, zeldin@niehs.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 9, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-26341 Filed 10-15-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2015-0950]

Sewage Treatment Technology—Type Approval of Marine Sanitation Devices

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Coast Guard will conduct a public workshop in Washington, DC to discuss sewage treatment technologies, issues concerning testing of marine sanitation devices for type approval, and issues concerning gray water. This workshop is intended to be an interactive exchange of information between policymakers, industry experts, and interested members of the public.

DATES: The workshop will be held on Tuesday and Wednesday, December 8 and 9, 2015 beginning at 9:30 a.m. and ending at 4 p.m., Eastern Time. This workshop is open to the public. Please note that the workshop has a limited number of seats and may close early if all business is finished. Contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) by December 4, 2015 to reserve seating. The comment period for the docket closes January 9, 2016.

ADDRESSES: The workshop will be held in conference rooms 8, 9, and 10 of the Department of Transportation Headquarters Building, 1200 New Jersey Ave. SE., Washington, DC 20590. The building is accessible by public transportation (Navy Yard subway station) or taxi. Parking for privately-owned vehicles is available nearby. Due to security requirements, each visitor must present a valid government-issued photo identification (for example, a driver's license) in order to gain entrance to the building. Contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) to facilitate the security process related to building access, or to request reasonable accommodation.

You may submit comments identified by docket number USCG-2015-0950 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See **SUPPLEMENTARY INFORMATION** for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the workshop, please call or email Mr. Wayne Lundy, U.S. Coast Guard; telephone 202-372-1379, email Wayne.M.Lundy@uscg.mil or Ms. Katherine Weiler, Environmental Protection Agency; telephone 202-566-1280, email Weiler.Katherine@epa.gov.

SUPPLEMENTARY INFORMATION: Your comment is important to us. If you submit a comment, please include the docket number shown at the beginning of this notice and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact us (see **FOR FURTHER INFORMATION CONTACT**) for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

This workshop is sponsored by the Coast Guard and the Environmental Protection Agency and is intended to be an interactive exchange of information between policymakers, industry experts, and interested members of the public. The primary topics that will be discussed include:

- Sewage treatment technologies;
- Issues concerning testing of marine sanitation devices for type approval;
- Simple on board checks for verifying performance of marine sanitation devices;
- Impact of gray water on the environment;
- Impact on the ship from processing gray water;
- Technologies for processing of gray water;
- Analytes for considering technologies treating gray water;
- Issues associated with existing federal standards and MARPOL Annex IV equipment standards (International Maritime Organization (IMO) resolution MEPC.227(64));
- Impact of No Discharge Zones; and
- Revision of an industry consensus standard, ASTM F2363—"Standard Specification for Sewage and Graywater Flow Through Treatment Systems".

Please note that the workshop has a limited number of seats and may close early if all business is finished.

We encourage you to participate and join in discussions, subject to the discretion of the moderator. If you wish to attend the meeting via teleconference, arrange for assistance in attending the meeting in person, or make a presentation, contact us (see **FOR FURTHER INFORMATION CONTACT**; audiovisual arrangements will be available). If you bring written comments to the workshop, you may submit them at the meeting and we will place them on our docket.

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

Dated: 13 October, 2015.

J. G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2015-26363 Filed 10-15-15; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2015-0960]

Coast Guard Acceptance of Sewage Treatment Plants for Type-Approval to International Maritime Organization Resolution MEPC.227(64)

AGENCY: Coast Guard, DHS.

ACTION: Notice of Policy and request for comments.

SUMMARY: The Coast Guard announces its acceptance of sewage treatment plants (also referred to as marine sanitation devices) for type-approval to International Maritime Organization resolution MEPC.227(64) as meeting the requirements for marine sanitation devices. This action will allow manufacturers as well as shipowners and operators the option to take advantage of building and using equipment that meets both domestic and international requirements while also benefitting the environment. The Coast Guard is also seeking information on simple on board checks to verify performance of sewage treatment plants.

DATES: Comments and related material must be received by the Coast Guard on or before November 16, 2015.

You may submit comments identified by docket number USCG-2015-0880 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Wayne M. Lundy, CG-ENG-3, U.S. Coast Guard; telephone 202-372-1379, email Wayne.M.Lundy@uscg.mil.

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this notice as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We are also planning to hold a two-day public workshop in Washington DC in the fall of 2015. We will issue a separate **Federal Register** notice to announce the date, time, and location of such a workshop. The purpose of the workshop will be to discuss sewage treatment technologies, issues concerning testing of marine sanitation devices for type approval and information on simple on board checks to verify performance of a marine sanitation device. The workshop will also consider issues associated with existing federal standards and MARPOL Annex IV equipment standards (resolution MEPC.227(64)), impact of No Discharge Zones, and issues concerning gray water.

Background and Purpose

Title 33 of the Code of Federal Regulations (CFR), part 159, prescribes requirements for the design and construction of marine sanitation devices ("MSDs", also referred to as

sewage treatment plants) and procedures for certifying that MSDs meet the regulations and standards of the Environmental Protection Agency promulgated under Section 312 of the Federal Water Pollution Control Act (Pub. L. 92-500, § 312, 86 Stat. 871 (October 18, 1972), *as amended*; *classified* to 33 U.S.C. 1322). In October 2012, the International Maritime Organization (IMO) adopted resolution MEPC.227(64)—*2012 Guidelines on implementation of effluent standards and performance tests for sewage treatment plants*. The International Convention on the Prevention of Pollution from Ships 73/78 (MARPOL) Annex IV requires sewage treatment plants to be type-approved taking into account the standards of IMO Resolution MEPC.227(64). While the United States is not a Contracting Government to MARPOL Annex IV, we recognize that the limits and standards in IMO resolution MEPC.227(64) are more stringent or prescriptive than those requirements in 33 CFR 159 concerning threshold limits and testing of equipment and thus equipment that is type-approved to the MEPC.227(64) standards would also satisfy U.S. threshold effluent limits. Specifically, we have determined that a MSD meeting the design specifications in MEPC.227(64) would exceed the performance specifications for Type II tanks, as listed in 33 CFR 159.53(b), which states that, "[u]nder the test conditions described in §§ 159.126 and 159.126a, [the tanks must] produce an effluent having a fecal coliform bacteria count not greater than 200 per 100 milliliters and suspended solids not greater than 150 milligrams per liter."

In recognition of this, the Coast Guard believes MSDs type-approved in accordance with the requirements of IMO resolution MEPC.227(64) and installed on U.S. flagged ships comply with those threshold effluent limits in 33 CFR 159.53(b). MSDs must still meet the other requirements contained in part 159, and any inconsistencies between part 159 and MEPC.227(64) must be resolved in favor of part 159. Manufacturers may submit their equipment to a recognized testing facility recognized by the Coast Guard for testing of such equipment and may make a submission to the Coast Guard requesting type approval.

Resolution MEPC.227(64) also contains a process allowing the Coast Guard to certify that a type-approved MSD meets the specific effluent discharge requirements for a vessel to enter Special Areas listed in MARPOL Annex IV. The Coast Guard would certify that the MSD meets the enhanced

effluent discharge and treatment specifications listed in MEPC.227(64). Under MARPOL Annex IV Regulations 9.1.1 and 9.1.2, vessels with MSDs conforming to the Special Area specifications contained in MEPC.227(64) may be permitted to operate in Special Areas. This certification would allow U.S.-flagged vessels to document that they meet those standards.

However, U.S.-flagged vessels voluntarily installing MSDs in accordance with MARPOL Annex IV standards must comply with the U.S. application of MEPC.227(64), as follows, to receive U.S. certification. Currently, MEPC.227(64), is vague on the amount of reduction required for thermotolerant coliform (TC), total suspended solids (TSS), biochemical oxygen demand without nitrification (BOD₅) and chemical oxygen demand (COD). While Section 3 of MEPC.227(64) states that “[i]n meeting the effluent standards in Section 4, an approved sewage

treatment plant should not rely solely on dilution of wastewater,” there are no specific levels of reduction given for TC, TSS, BOD₅ and COD (unlike the specific Percent Reductions given for discharges of nitrogen and phosphorus in Section 4.2).

IMO Resolution MEPC.227(64) states that an approved MSD not rely solely on dilution of wastewater in order to meet the effluent limits stipulated in resolution MEPC.227(64). Resolution MEPC.227(64) further states that, where amounts of dilution are deemed essential to a treatment process, the effluent standards in Section 4 should be adjusted proportionally using dilution compensation factor Q_i/Q_e to account for dilution Q_d .¹ In order to demonstrate that the MSD does not rely solely on dilution of wastewater in order to meet the effluent standards, the effluent concentration value C_e for any particular analyte addressed in resolution MEPC.227(64), Section 4.1 (specifically, TC, TSS, BOD₅ and COD)

will need to be less than the effluent standard for that analyte multiplied by the dilution compensation factor Q_i/Q_e .

In order for a MSD to be able to be technically evaluated for type approval under MEPC.227(64), the concentration value of the effluent for that analyte being considered must be readable, *i.e.*, at or above the detection limit for the test method for that analyte. For consideration by the Coast Guard, a MSD, after application of the dilution compensation factor Q_i/Q_e , the revised effluent concentration value of any analyte measured at the Effluent Sample Point as shown in figure 1 of this Notice of Policy cannot be below the Test Method detection limit for that analyte. Figure 1 is replicated from resolution MEPC.227(64). If the revised concentration value is below the Test Method detection limit for that analyte, then it becomes impossible for the concentration value to be physically measured.

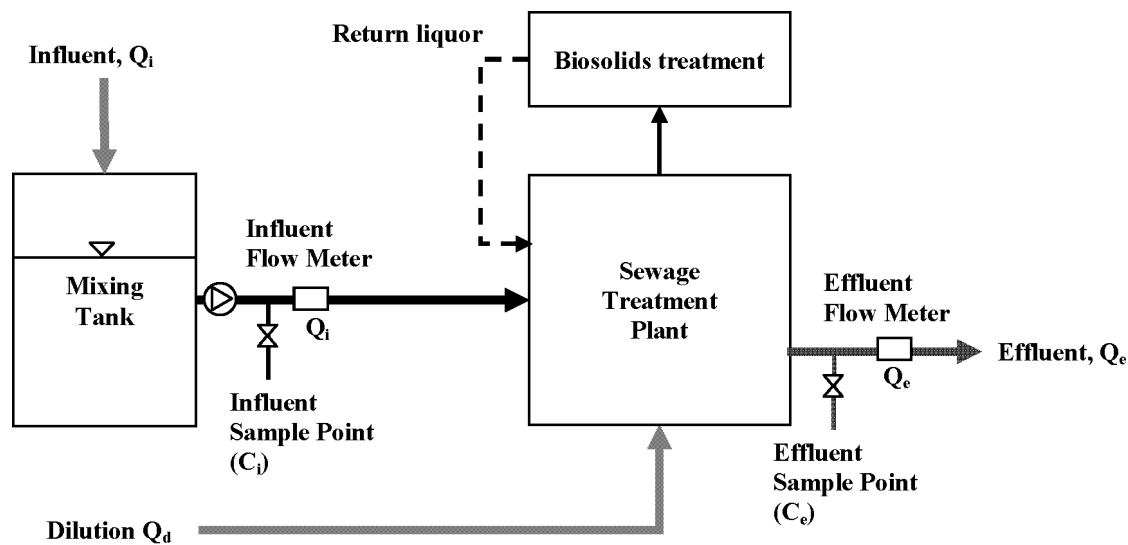


Figure 1: System diagram of a sewage treatment plant

To make the above determination for Annex IV certification, the Coast Guard will use the approved test methods that are listed in the Environmental

Protection Agency regulations (40 CFR 136, Guidelines Establishing Test Procedures for the Analysis of

Pollutants). The following methods must be used:

- Thermotolerant Coliform (TC) Test Method EPA 600/8–78–017 Chapter III²

¹ Dilution (Q_d)—is dilution water, grey water, process water, and/or seawater introduced to the sewage treatment plant after the influent sample point and after the influent flow measurement device, see figure 1 of resolution MEPC.227(64).

Effluent (Q_e)—is treated wastewater produced by the sewage treatment plant, see figure 1 of resolution MEPC.227(64).

Influent (Q_i)—is liquid containing sewage, grey water or other liquid streams, to be processed by the

treatment plant, see figure 1 of resolution MEPC.227(64).

² Please refer to Page Number 124 in document USEPA. 1978. Microbiological Methods for Monitoring the Environment, Water, and Wastes. Environmental Monitoring and Support Laboratory, U.S. Environmental Protection Agency, Cincinnati, Ohio. EPA/600/8–78/017; weblink: <http://nepis.epa.gov/Exe/ZyNET.exe/300014TD.txt?ZyActionD=ZyDocument&Client=EPA&Index=1976%20Thru%201980&Docs=&Query=&Time=>

[&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5CZYFILES%5CINDEX%20DATA%5C76THRU80%5CTXT%5C000000%5C300014TD.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&](#)

(Detection Limit = 1 colony form unit (CFU)/100 mL),

- Total Suspended Solids (TSS) Test Method 160.2 (Detection Limit = 4.0 mg/L),

- Biochemical Oxygen Demand (BOD₅) without nitrification³ Test Method 5210 B³ (Detection Limit = 2.0 mg/L),

- Chemical Oxygen Demand (COD) Test Method 410.4 (Detection Limit = 3.0 mg/L),

- pH Test Method 150.1 (none stated but not normally reported below 0.01),⁴

- Total Nitrogen⁵ 351.2 (Detection Limit = 0.5 mg/L),

- Total Phosphorus Test Method 365.2 (Detection Limit = 0.01 mg/L) and Disinfectant residual

- Chlorine Test Method 330.5 (Detection Limit = 0.2 mg/L)

The Coast Guard is also seeking information on possible simple on board checks that may be available and easily used to verify performance of a sewage treatment plant with effluent requirements.

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

Dated: October 9, 2015.

F.J. Sturm,

Deputy Director, Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2015-26285 Filed 10-15-15; 8:45 a.m.]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2015-0001; Internal Agency Docket No. FEMA-B-1534]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1.

³ The equivalent U.S. EPA Test Method for Biochemical Oxygen Demand (BOD₅) without nitrification is done as carbonaceous biochemical oxygen demand (CBOD₅) and should not be confused with the traditional BOD₅ test method which measures "total BOD". The addition of the nitrification inhibitor is not a procedural option, but must be included to report the CBOD₅ parameter.

⁴ There is no US EPA Test Method listed in 40 CFR 136 so the US EPA has adopted American Public Health Association (APHA) Standard Methods for the Examination of Water and Wastewater. The current edition is the 22nd edition.

⁵ Total Nitrogen means the sum of total Kjeldahl nitrogen (organic and ammoniacal nitrogen) nitrate-nitrogen and nitrite-nitrogen.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance

and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) Luis.Rodriguez3@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: August 28, 2015.

Roy E. Wright,*Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Alabama: Tuscaloosa	City of Tuscaloosa (15-04-0628P).	The Honorable Walter Maddox, Mayor, City of Tuscaloosa, 2201 University Boulevard, Tuscaloosa, AL 35401.	Engineering Department, 2201 University Boulevard, Tuscaloosa, AL 35401.	http://www.msc.fema.gov/lomc .	Oct. 23, 2015	010203
Tuscaloosa	City of Tuscaloosa (15-04-4630P).	The Honorable William P. Kenoi, Mayor, County of Hawaii, 25 Aupuni Street, Hilo, HI 96720.	Engineering Department, 2201 University Boulevard, Tuscaloosa, AL 35401.	http://www.msc.fema.gov/lomc .	Oct. 21, 2015	155166
Tuscaloosa	Unincorporated areas of Tuscaloosa County (15-04-0628P).	The Honorable W. Hardy Mccollum, Chairman, Tuscaloosa County Board of Commissioners, 714 Greensboro Avenue, Tuscaloosa, AL 35402.	Tuscaloosa County Engineering Department, 2810 35th Street, Tuscaloosa, AL 35401.	http://www.msc.fema.gov/lomc .	Oct. 23, 2015	010201
Colorado: Jefferson	City of Golden (15-08-0786P).	The Honorable Marjorie Sloan, Mayor, City of Golden, 911 10th Street, Golden, CO 80401.	Public Works Department, 1445 10th Street, Golden, CO 80401.	http://www.msc.fema.gov/lomc .	Oct. 23, 2015	080090
Teller	City of Woodland Park (15-08-0099P).	The Honorable Neil Levy, Mayor, City of Woodland Park, P.O. Box 9007, Woodland Park, CO 80866.	City Hall, 220 West South Avenue, Woodland Park, CO 80866.	http://www.msc.fema.gov/lomc .	Oct. 22, 2015	080175
Montana: Gallatin	City of Bozeman (15-08-0124P).	The Honorable Jeff Krauss, Mayor, City of Bozeman, P.O. Box 1230, Bozeman, MT 59771.	Public Works Department, 20 East Olive Street, Bozeman, MT 59771.	http://www.msc.fema.gov/lomc .	Oct. 23, 2015	300028
Stillwater	Town of Columbus (15-08-0781P).	The Honorable Gary Woltermann, Mayor, Town of Columbus, P.O. Box 549, Columbus, MT 59019.	Stillwater County West Annex, 431 Quarry Road, Columbus, MT 59019.	http://www.msc.fema.gov/lomc .	Oct. 19, 2015	300109
North Carolina: Randolph	Unincorporated areas of Randolph County (15-04-3243P).	The Honorable Darrell L. Frye, Chairman, Randolph County Board of Commissioners, P.O. Box 4728, Asheboro, NC 27204.	Randolph County Department of Planning and Development, 204 East Academy Street, Asheboro, NC 27203.	http://www.msc.fema.gov/lomc .	Oct. 22, 2015	370195
North Dakota: Cass	City of Fargo (15-08-0016P).	The Honorable Tim Mahoney, Mayor, City of Fargo, 200 3rd Street North, Fargo, ND 58102.	City Hall, 200 3rd Street North, Fargo, ND 58102.	http://www.msc.fema.gov/lomc .	Nov. 3, 2015	385364
Texas: Bell	City of Temple (15-06-1800P).	The Honorable Danny Dunn, Mayor, City of Temple, 2 North Main Street, Suite 103, Temple, TX 76501.	Department of Public Works, Engineering Division, 3210 East Avenue H, Building A, Suite 107, Temple, TX 76501.	http://www.msc.fema.gov/lomc .	Nov. 3, 2015	480034
Bexar	City of San Antonio (14-06-3172P).	The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	http://www.msc.fema.gov/lomc .	Oct. 15, 2015	480045
Denton	City of Denton (14-06-3408P).	The Honorable Chris A. Watts, Mayor, City of Denton, 215 East McKinney Street, Denton, TX 76201.	Engineering Department, 901-A Texas Street, Denton, TX 76509.	http://www.msc.fema.gov/lomc .	Nov. 4, 2015	480194
Denton	City of Denton (15-06-0979P).	The Honorable Chris A. Watts, Mayor, City of Denton, 215 East McKinney Street, Denton, TX 76201.	Engineering Department, 901-A Texas Street, Denton, TX 76509.	http://www.msc.fema.gov/lomc .	Oct. 19, 2015	480194

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Harris	City of Houston (14-06-4559P).	The Honorable Annise D. Parker, Mayor, City of Houston, P.O. Box 1562, Houston, TX 77251.	Floodplain Management Office, 1002 Washington Avenue, 3rd Floor, Houston, TX 77002.	http://www.msc.fema.gov/lomc .	Oct. 16, 2015	480296
Harris	City of Pasadena (14-06-4559P).	The Honorable Johnny Isbell, Mayor, City of Pasadena, 1211 Southmore Avenue, Pasadena, TX 77502.	Engineering Department, 1114 Davis Street, 2nd Floor, Pasadena, TX 77506.	http://www.msc.fema.gov/lomc .	Oct. 16, 2015	480307
Harris	Unincorporated areas of Harris County (15-06-1289P).	The Honorable Ed M. Emmett, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Permit Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77092.	http://www.msc.fema.gov/lomc .	Oct. 30, 2015	480287
Hunt	City of Greenville (14-06-4302P).	The Honorable Steve Reid, Mayor, City of Greenville, P.O. Box 1049, Greenville, TX 75403.	Public Works Department, 2315 Johnson Street, Greenville, TX 75401.	http://www.msc.fema.gov/lomc .	Jul. 8, 2015	485473
Tarrant	City of Fort Worth (14-06-4046P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	City Hall, 1000 Throckmorton Street, Fort Worth, TX 76102.	http://www.msc.fema.gov/lomc .	Sep. 15, 2015	480596
Tarrant	City of Fort Worth (15-06-0295P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	City Hall, 1000 Throckmorton Street, Fort Worth, TX 76102.	http://www.msc.fema.gov/lomc .	Aug. 25, 2015	480596
Travis	Unincorporated areas of Travis County (15-06-1733P).	The Honorable Sarah Eckhardt, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Office of Emergency Management Services, 5010 Old Manor Road, Austin TX 78723.	http://www.msc.fema.gov/lomc .	Oct. 28, 2015	481026
Virginia: Independent City.	City of Salem (14-03-3079P).	The Honorable Byron Foley, Mayor, City of Salem, 114 North Broad Street, Salem, VA 24153.	Engineering and Inspections Department, 25 East Main Street, Salem, VA 24153.	http://www.msc.fema.gov/lomc .	Oct. 9, 2015	510141

[FR Doc. 2015-26375 Filed 10-15-15; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2015-0001; Internal Agency Docket No. FEMA-B-1533]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency

Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the

community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) Luis.Rodriguez3@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at

www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The

flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below.

Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: August 28, 2015.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Illinois:						
Adams	City of Quincy, (15-05-4067P).	The Honorable Kyle Moore, Mayor, City of Quincy, 730 Maine Street, Quincy, IL 62301.	Quincy City Hall, 730 Maine Street, Quincy, IL 62301.	http://www.msc.fema.gov/lomc .	Sept. 24, 2015 ...	170003
Adams	Unincorporated areas of Adams County, (15-05-4067P).	The Honorable Les Post, Chairman, Adams County Board, 101 North 54th Street, Quincy, IL 62305.	Adams County Highway Department, 101 North 54th Street, Quincy, IL 62305.	http://www.msc.fema.gov/lomc .	Sept. 24, 2015 ...	170001
Indiana:						
Allen	Unincorporated areas of Allen County, (15-05-5235P).	Commissioner Nelson Peters, Allen County, Board of Commissioners, Citizens Square, 200 East Berry Street, Suite 410, Fort Wayne, IN 46802.	200 East Berry Street, Suite 150, Fort Wayne, IN 46802.	http://www.msc.fema.gov/lomc .	Nov. 27, 2015 ...	180302
Missouri:						
Jackson	City Of Lee's Summit, (15-07-1190P).	The Honorable Randy Rhoads, Mayor, City of Lee's Summit, 220 Southeast Green Street, Lee's Summit, MO 64063.	207 Southwest Market Street, Lee's Summit, MO 64063.	http://www.msc.fema.gov/lomc .	Nov. 26, 2015 ...	290174
Jefferson	Unincorporated areas of Jefferson County, (15-07-0620P).	Mr. Ken Walker, Jefferson County Executive, Jefferson County Administration Center, 729 Maple Street, Suite G30, Hillsboro, MO 63050.	729 Maple Street, Suite G30, Hillsboro, MO 63050.	http://www.msc.fema.gov/lomc .	Nov. 13, 2015 ...	290808
Utah:						
Uintah	City Of Vernal, (14-08-0909P).	The Honorable Sonja Norton, Mayor, City of Vernal, 374 East Main Street, Vernal, UT 84078.	447 East Main Street, Vernal, UT 84078.	http://www.msc.fema.gov/lomc .	Nov. 25, 2015 ...	490149
Uintah	Unincorporated areas of Uintah County, (14-08-0909P).	The Honorable Mike McKee, Commissioner, Uintah County, 152 East 100 North, Vernal, UT 84078.	152 East 100 North, Vernal, UT 84078.	http://www.msc.fema.gov/lomc .	Nov. 25, 2015 ...	490147
Virginia:						
Prince William	City Of Manassas, (15-03-1081P).	The Honorable Harry J. Parrish, II, Mayor, City of Manassas, 9027 Center Street, Manassas, VA 20110.	Manassas City Engineer's Office, 9027 Center Street, Suite 203, Manassas, VA 20110.	http://www.msc.fema.gov/lomc .	Nov. 19, 2015 ...	510122

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Prince William	Unincorporated areas of Prince William County, (15-03-1081P).	Mr. Corey A. Stewart, Chairman, Board of County Supervisors, One County Complex Court, Prince William, VA 22192.	Prince William County Department of Public Works, Watershed Management Division, 4379 Ridgewood Center Drive, Prince William, VA 22192.	http://www.msc.fema.gov/lomc .	Nov. 19, 2015 ...	510119

[FR Doc. 2015-26374 Filed 10-15-15; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5828-N-42]

Federal Property Suitable as Facilities To Assist the Homeless

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

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402-3970; TTY number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been

reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B-17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other

purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Agriculture:* Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720-8873; *Army:* Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571) 256-8145; *Energy:* Mr. David Steinau, Department of Energy, Office of Property Management, OECM MA-50, 4B122, 1000 Independence Ave. SW., Washington, DC 20585 (202) 287-1503; *GSA:* Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501-0084; *Interior:* Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 3960 N. 56th Ave. #104, Hollywood, FL. 33021; (443) 223-4639; *Navy:* Mr. Steve Matteo, Department of the Navy, Asset Management; Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685-9426; (These are not toll-free numbers).

Dated: October 7, 2015.

Brian P. Fitzmaurice,
Director, Division of Community Assistance,
Office of Special Needs Assistance Programs.

**TITLE V, FEDERAL SURPLUS PROPERTY
PROGRAM FEDERAL REGISTER REPORT
FOR 10/16/2015**

Suitable/Available Properties

Building

Michigan

Former Newport Nike Missile
Site D-58

800 East Newport Road
Newport MI 48166

Landholding Agency: GSA
Property Number: 54201530010

Status: Excess

GSA Number: 1-D-MI-0536

Directions: Disposal Agency: GSA;
Landholding Agency: COE

Comments: 70+ yrs. old; 3 buildings totaling
11,447 sq. ft.; sits on 36.35 acres;
industrial; training site; extremely poor/
hazardous condition; remediation required;
contact GSA for more information.

North Carolina

Tract 01-160

115 British Lakes

Greensboro NC 27410

Landholding Agency: Interior
Property Number: 61201530027

Status: Unutilized

Comments: off-site removal only; no future
agency need; 1,271 sq. ft.; residential: very
poor conditions; lead & aspects; contact
interior for more information.

4 Buildings

Green Acres Lane

Greensboro NC 27410

Landholding Agency: Interior

Property Number: 61201530028

Status: Unutilized

Directions: tract 01-151 (1,002 sq. ft.), Tract
01-152 (1,612 sq. ft.), Tract 01-158 (1,822
sq. ft.), Tract 01-163A (1,318 sq. ft.)

Comments: off-site removal only; no future
agency need residential; leaking
underground heating tanks; lead &
asbestos; contact Interior for more
information on a specific property.

Trace 01-163B

3609 Battleground Road

Greensboro NC 27410

Landholding Agency: Interior

Property Number: 61201530029

Status: Unutilized

Comments: off-site removal only; no future
agency need; 1,020 sq. ft.; residential; lead
& asbestos; leaking underground heating
tanks; contact Interior for more
information.

Wisconsin

Canthook Lake—House/Storage

Canthook Lake

Iron River WI

Landholding Agency: GSA

Property Number: 54201530009

Status: Excess

GSA Number: 1-A-WI-0624-AA

Directions: Disposal Agency: GSA; Land
Holding Agency: Agriculture

Comments: off-site removal only; 70+ yrs.
old; 4,004 sq. ft.; residential; average
condition; contact GSA for more
information.

Land

California

FAA Sacramento Middle Maker
Site

1354 Palomar Circle

Sacramento CA 95831

Landholding Agency: GSA

Property Number: 54201530007

Status: Surplus

GSA Number: 9-U-CA-1707-AA

Directions: Disposal Agency: GSA;

Landholding Agency: FAA

Comments: 0.29 Acres; contact GSA for more
information.

Guam

Andersen Administrative Annex (Andy
South)

Marine Corps Dr. & Turner Street

Yigo GU

Landholding Agency: Navy

Property Number: 77201530027

Status: Unutilized

Comments: 43,560 sq. ft. portion of Anderson
Administrative Annex is occupied by the
Guam Fire Dept. contact Navy for more
information.

Unsuitable Properties

Building

Alaska

NMFS Combine Building

Priblof Island

St. Paul AK 99660

Landholding Agency: GSA

Property Number: 54201530008

Status: Unutilized

GSA Number: 9-C-AK-46622-S

Directions: Disposal Agency: GSA;

Landholding Agency: NOAA

Comments: property is inaccessible because
it is located on a (small) off-shore island;
property located within floodway which
has not been correct or contained only
accessible by sea plane.

Reasons: Floodway

New York

Building 1438

West Point; Range Rd. (Range 8)

West Point NY 10996

Landholding Agency: Army

Property Number: 21201530095

Status: Unutilized

Comments: RE-DETERMINATION:

structurally unsound; attempt of removal
will most likely result in collapse of bldg.;
clear threat to personal physical safety.

Reasons: Extensive deterioration

5 Buildings

Brookhaven National Laboratory

Upton NY 11973

Landholding Agency: Energy

Property Number: 41201530007

Status: Excess

Directions: Building 562, 950, 954, 180, 355

Comments: public access denied and no
alternative method to gain access without
compromising National Security.

Reasons: Secured Area

Oregon

JC, Trailer #12 Bldg. ID 1202

59868 East Hwy. 224

Estacada OR 97023

Landholding Agency: Agriculture

Property Number: 15201530049

Status: Underutilized

Directions: 060610 1617 Timber Lake Job
Corps CCC

Comments: documented deficiencies; severe
structural damages; building collapsing;
represents a clear threat to personal
physical safety.

Reasons: Extensive deterioration

JC, Trailer #19 Bldg. ID 1195

59868 East Hwy. 224

Estacada OR 97023

Landholding Agency: Agriculture

Property Number: 15201530050

Status: Underutilized

Directions: 060610 1617 Timber Lake Job
Corps CCC

Comments: documented deficiencies; severe
structural damages; building collapsing;
represents a clear threat to personal
physical safety.

Reasons: Extensive deterioration

JC, Trailer #11 Bldg. ID 1191

59868 East Hwy. 224

Estacada OR 97023

Landholding Agency: Agriculture

Property Number: 15201530052

Status: Underutilized

Directions: 060610 1617 Timber Lake Job
Corps CCC

Comments: documented deficiencies; severe
structural damages; building collapsing;
represents a clear threat to personal
physical safety.

Reasons: Extensive deterioration

JC, Trailer #10 Bldg. ID 1203

59868 East Hwy. 224

Estacada OR 97023

Landholding Agency: Agriculture

Property Number: 15201530053

Status: Underutilized

Directions: 060610 1617 Timber Lake Job
Corps CCC

Comments: documented deficiencies; severe
structural damage; building collapsing;
represents a clear threat to personal
physical safety.

Reasons: Extensive deterioration

JC, Trailer #29 Bldg. ID 1198

59868 East Hwy.

Estacada OR 97023

Landholding Agency: Agriculture

Property Number: 15201530054

Status: Underutilized

Directions: 060610 1617 Timber Lake Job
Corps CCC

Comments: documented deficiencies; severe
structural damage; building collapsing;
represents a clear threat to personal
physical safety.

Reasons: Extensive deterioration

JC, Trailer #25 Bldg. ID 1200

59868 East Hwy. 224

Estacada OR 97023

Landholding Agency: Agriculture

Property Number: 15201530055

Status: Underutilized

Directions: 060610 1617 Timber Lake Job
Corps CCC

Comments: documented deficiencies; severe
structural damage; building collapsing;

represents a clear threat to personal physical safety.
 Reasons: Extensive deterioration
 JC, Trailer #22 Bldg. ID 1197
 59868 East Hwy. 224
 Estacada OR 97023
 Landholding Agency: Agriculture
 Property Number: 15201530056
 Status: Underutilized
 Directions: 060610 1617 Timber Lake Job Corps CCC
 Comments: documented deficiencies: severe structural damage; building collapsing; represents a clear threat to personal physical safety.
 Reasons: Extensive deterioration
 JC, Trailer #26 Bldg. ID 1199
 59868 East Hwy. 224
 Estacada OR 97023
 Landholding Agency: Agriculture
 Property Number: 15201530057
 Status: Underutilized
 Directions: 060610 1617 Timber Lake Job Corps CCC
 Comments: documented deficiencies: severe structural damage; building collapsing; represents a clear threat to personal physical safety.
 Reasons: Extensive deterioration

Virginia

CEP-41, Destroyer Squadron
 1520 Gilbert Street
 Norfolk VA 23511
 Landholding Agency: Navy
 Property Number: 77201530028
 Status: Excess
 Comments: public access denied and no alternative method to gain access without compromising national security.
 Reasons: Secured Area

[FR Doc. 2015-26014 Filed 10-15-15; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO923000-L1440000-ET0000-15X]

Application for Withdrawal and Opportunity for Public Meeting, Deep Creek Canyon and Corridor, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States Forest Service (USFS) has filed an application (COC 77206) with the Bureau of Land Management (BLM) requesting the Secretary of the Interior to withdraw approximately 4,200 acres of National Forest System lands within the White River National Forest from location and entry under the United States mining laws for a period of 20 years to protect multiple outstanding features, including scenic, recreational, geologic, ecologic, wildlife, and fisheries values, in the Deep Creek canyon and corridor.

The character of the canyon and corridor is natural and essentially primitive, and the lands and free-flowing waters were found to be eligible for Wild and Scenic designation under the Wild and Scenic Rivers Act in the 2002 White River National Forest, Land and Resource Management Plan Revision. The Forest Plan decision recommended withdrawal of the canyon and corridor from location and entry under the United States mining laws.

This notice temporarily segregates the land for up to 2 years from location and entry under the United States mining laws while the application is being processed. This notice also provides the public an opportunity to comment on the application and to request a public meeting. The lands have been and will remain open to mineral and geothermal leasing, and to such forms of disposition as may be allowed by law on National Forest System lands.

DATES: Comments and public meeting requests must be received by January 14, 2016.

ADDRESSES: Comments and meeting requests should be sent to Steve Craddock, Branch of Lands and Realty, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, CO 80215-7093.

FOR FURTHER INFORMATION CONTACT: Steve Craddock, BLM Colorado State Office, 303-239-3707, or Carole Huey, White River National Forest, 970-945-3219, during regular business hours 7:45 a.m. to 4:15 p.m., Monday through Friday, except holidays. 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. 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 USFS has filed an application with the BLM pursuant to the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, requesting the Secretary of the Interior to withdraw the following described National Forest System lands from location and entry under the United States mining laws (30 U.S.C. Ch. 2), but not from leasing under the mineral or geothermal leasing laws, for a period of 20 years, subject to valid existing rights:

White River National Forest

Sixth Principal Meridian

T. 4 S., R. 87 W.,

sec. 6, beginning at a point on the west line of Section 6 from which the corner

common to Sections 6 and 7 bears South a distance of 2665 feet, thence S.65°E. a distance of 1100 feet; thence N.55°E. a distance of 400 feet; thence N.15°E. a distance of 800 feet; thence N.40°W. a distance of 600 feet; thence N.10°W. a distance of 1100 feet; thence N.40°E. a distance of 600 feet; thence S.20°E. a distance of 1300 feet; thence S.30°E. 1300 feet; thence S.30°W. a distance of 800 feet; thence South a distance of 800 feet; thence S.45°E. a distance of 1500 feet; thence N.75°E. a distance of 1300 feet; thence South a distance of 750 feet to the south line of said Section 6; thence S.89°52' W., along the south line of Section 6, a distance of 4452 feet to the corner on the township line common to Sections 6 and 7; thence North, along the west township line, a distance of 2665 feet to the Point of Beginning;

sec. 7, beginning at the corner common to Sections 6 and 7 on the west township line; thence N.89°52'E., along the north line of Section 7, a distance of 4452 feet, thence South a distance of 1150 feet to a point at 9450 feet elevation, thence S.50°E. a distance of 350 feet; thence S.55°E. a distance of 2000 feet; thence S.10°E. a distance of 200 feet; thence South a distance of 700 feet; thence S.40°E. a distance of 668 feet to a point on the east line of Section 7; thence S.89°50'W., along the south line of Section 7 a distance of 4614 feet; thence N.30°E. a distance of 280 feet; thence N.65°W. a distance of 1100 feet; thence North a distance of 50 feet; thence N.50°E. a distance of 1550 feet; thence N.25°W. a distance of 300 feet; thence N.75°W. a distance of 1300 feet; thence N.45°W. a distance of 300 feet; thence North a distance of 200 feet; thence N.80°E. a distance of 1200 feet; thence N.15°W. a distance of 500 feet; thence N.75°W. a distance of 900 feet; thence N.50°W. a distance of 2000 feet to the west line of Section 7; thence North, along the west line of Section 7 a distance of 286 feet to the Point of Beginning;

sec. 8, beginning at corner common to Sections 8 and 17 only; thence N.0°08'W., along the west line of Section 8, a distance of 830 feet; thence S.40°E. a distance of 30 feet; thence S.70°E. a distance of 700 feet; thence S.30°W. a distance of 600 feet; thence S.20°E. a distance of 60 feet to a point on the south line of Section 8; thence West, along the south line of Section 8, a distance of 420 feet to the Point of Beginning;

sec. 17, W¹/₂W¹/₂W¹/₂SW¹/₄;

sec. 18., E¹/₂W¹/₂NE¹/₄, E¹/₂NE¹/₄, E¹/₂SE¹/₄;

Sec. 19, NE¹/₄NE¹/₄, E¹/₂SE¹/₄NE¹/₄,

E¹/₂NE¹/₄SE¹/₄;

Sec. 20, S¹/₂NE¹/₄,SE¹/₄, N¹/₂SE¹/₄SW¹/₄, NW¹/₄SE¹/₄SW¹/₄, N¹/₂SW¹/₄, S¹/₂NW¹/₄, NW¹/₄NW¹/₄;

sec. 21. lot 4, W¹/₂SW¹/₄, SW¹/₄NW¹/₄;

sec. 28, beginning at the corner common to Sections 20, 21, 28 and 29, thence S.89°47'E. along the north section line of Section 28, a distance of 1317 feet; thence S.0°02.5'E. a distance of 1616 feet to a point on the north line of Tract 40;

- thence West, along said north line of Tract 40, a distance of 400 feet to Angle Point 2 of said Tract 40; thence N.40°W. a distance of 180 feet; thence S.70°W. a distance of 900 feet to a point on the west line of Section 28; thence N0°02'W. along the west section line of Section 28 a distance of 1820 feet to the Point of Beginning;
- sec. 29, beginning at the section corner common to Sections 20, 21, 28 and 29; thence S.0°02'E. along the east line of Section 29 a distance of 1820 feet; thence S.75°W. a distance of 1100 feet; thence S.85°W. a distance of 100 feet; thence N.80°W. a distance of 400 feet; thence N.30°W. a distance of 400 feet; thence North a distance of 700 feet; thence N.10°W. a distance of 300 feet; thence N.55°W. a distance of 1500 feet to a point on the north line of Section 29; thence N.89°53'E. along the north line of Section 29 a distance of 3940 feet to the Point of Beginning.
- T. 3 S., R.88 W. (unsurveyed public lands), Beginning at the southeast corner of P.L.O. 1611, stated as being the southeast corner of the N $\frac{1}{2}$ S $\frac{1}{2}$ SW $\frac{1}{4}$ of Section 20, thence West, on and along the south boundary of P.L.O 1611, a distance of 1160 feet; thence S.20°W., leaving the boundary of P.L.O. 1611, a distance of 340 feet; thence S.5°E. a distance of 350 feet to a point of intersection with the 10460 contour elevation; thence S.30°E. a distance of 2000 feet; thence S.10°E. a distance of 950 feet to a point in White Owl Creek; thence S.60°E. a distance of 1100 feet; thence S.30°E. a distance of 1600 feet; thence S.35°E. a distance of 800 feet; thence S.55°E. a distance of 600 feet; thence S.85°E. a distance of 1800 feet; thence East a distance of 2000 feet; thence S85°E. a distance of 800 feet; thence S.80°E. a distance of 500 feet; thence S.30°E. a distance of 900 feet; thence S.20°E. a distance of 800 feet; thence S.80°E. a distance of 1350 feet; thence S.30°E. a distance of 300 feet; thence S.10°E. a distance of 300 feet; thence S.15°E. a distance of 400 feet; thence S.65°W. a distance of 1300 feet to a point in the center of a small drainage; thence S39°E. a distance of 1350 feet to a point at 10262 feet in elevation; thence S.28°E. a distance of 270 feet to a point on the south township line; thence East, on and along the south township line, a distance of 6100 feet; thence N.50°W. a distance of 3100 feet; thence N.30°W. a distance of 600 feet to a point; thence N.30°W. a distance of 1000 feet; thence N.35°W. a distance of 2300 feet; thence N.30°W. a distance of 700 feet; thence North a distance of 700 feet; thence N.55°E. a distance of 300 feet to a point in a drainage; thence N.75°W. a distance of 500 feet; thence N.30°W. 1500 feet to a point in the drainage of Short Creek; thence S.30°W. a distance of 500 feet; thence S.87°W. a distance of 900 feet; thence N.75°W. a distance of 700 feet; thence N.89°W. a distance of 900 feet to a point on the 10320 contour line; thence N.65°W. a distance of 600 feet; thence West a distance of 600 feet; thence S.65°W. a distance of 600 feet; thence S.80°W. a distance of 700 feet; thence N.80°W. a distance of 900 feet; thence N.50°W. a distance of 1450 feet; thence N.40°W. a distance of 1200 feet to a point on the 10570 contour line; thence N.50°W. a distance of 900 feet; thence N.60°W. a distance of 250 feet; thence N.45°W. a distance of 800 feet; thence N.30°W. a distance of 400 feet to a point on the 10600 elevation contour line; thence on and along said 10600 foot contour line a distance of 180 feet to a point of intersection with the east boundary of P.L.O 1611; thence South a distance of 390 feet to the Point of Beginning.
- T. 4 S., R. 88 W.,
- sec. 1, beginning at the corner on the east township line common to Sections 1 and 12, thence North on and along the east township line a distance of 2665 feet; thence N.15°W. a distance of 900 feet; thence N.65°W. a distance of 700 feet; thence S.75°W. a distance of 1600 feet; thence S.65°W. a distance of 1200 feet; thence N.65°W. a distance of 1900 feet to a point on the west line of Section 1; thence South, on and along the west line of Section 1, a distance of 3380 feet; thence S.15°E a distance of 145 feet to the south line of Section 1; thence S.89°57'E, on and along the south line of Section 1, a distance of 660 feet; thence N.70°W. a distance of 200 feet; thence N.80°E. a distance of 600 feet; thence N.88°E. a distance of 900 feet; thence N.55°E. a distance of 700 feet; thence S.85°E. 900 feet; Thence S. 65°E. a distance of 600 feet; thence S.50°E. a distance of 660 feet to a point on the south line of Section 1; thence S.89°57'E., on and along the south line of Section 1, a distance of 360 feet to the Point of Beginning;
- sec. 2, beginning at the corner common to Sections 2 and 3 on the North township line, thence S.0°09'E., on and along the west line of Section 2, a distance of 2815 feet; thence S.33°E. a distance of 2400 feet; thence S.50°E. a distance of 300 feet; thence S.83°E. a distance of 750 feet; thence N.70°E. a distance of 900 feet; thence East a distance of 400 feet; thence S.55°E. a distance of 900 feet to a point on the east line of Section 2; thence North, on and along the east line of Section 2, a distance of 3380 feet; thence N.40°W., a distance of 900 feet; thence N.60°W a distance of 1900 feet; thence N.40°W. a distance of 500 feet to a point on the north section line of Section 2; thence West, on and along the north line of Section 2, a distance of 2620 feet to the Point of Beginning;
- sec. 3, beginning at the corner common to Sections 2 and 3 on the north township line, thence West, along the north line of the township, a distance of 3480 feet; thence S.28°E. a distance of 2230 feet to a point in the Johnson Pasture Trail, Forest Service Trail Number 1852; thence N.85°E. a distance of 800 feet; thence East a distance of 400 feet; thence S.45°E. a distance of 1250 feet to a point on the east line of Section 3; thence N.0°09'W., on and along the east line of Section 3, a distance of 2815 feet to the Point of Beginning;
- sec. 12, beginning at a point on the north section line of Section 12 from which the corner common to Sections 1, 2, 11, and 12 bears N.89°57'W. a distance of 30 feet, thence S.15°E. a distance of 255 feet; thence N.70°E. a distance of 620 feet to a point on the North line of Section 12; thence N.89°57'W., on and along the north line of Section 12, a distance of 650 feet to the Point of Beginning; and Beginning at the corner common to Sections 1 and 12 on the east township line, thence N.89°57'W., on and along the north section line of Section 12, a distance of 360 feet; thence S.50°E. a distance of 465 feet to a point on the west line of Section 12; thence North, on and along the west line of Section 12, a distance of 286 feet to the Point of Beginning.

The areas described aggregate approximately 4,200 acres in Garfield County.

The purpose of the withdrawal is to protect multiple outstanding features, including scenic, recreational, geologic, ecologic, wildlife, and fisheries values, in the Deep Creek canyon and corridor.

The use of a right-of-way, interagency or cooperative management agreement would not adequately constrain non-discretionary uses that could irrevocably destroy the area's scenic and recreational values.

No alternative sites are feasible as the described lands contain the natural resource and recreation values in need of protection.

No water rights will be needed to fulfill the purpose of the proposed withdrawal.

For a period until January 14, 2016, all persons who desire to submit comments, suggestions, or objections in connection with the withdrawal application may present their views in writing to the BLM Colorado State Office at the address listed above. Comments, including names and street addresses of respondents, will be available for public review at the BLM Colorado State Office at the above address during regular business hours 7:45 a.m. to 4:15 p.m. Monday through Friday, except Federal holidays.

Notice is also hereby given that the opportunity for a public meeting is afforded in connection with the withdrawal application. All interested parties who desire a public meeting for the purpose of being heard on the proposed withdrawal application must submit a written request to the BLM Colorado State Office at the address listed above by January 14, 2016.

If the authorized officer decides that a public meeting will be held, a notice of the time and place will be published

in the **Federal Register** and in a newspaper of general circulation in the respective areas of the proposed withdrawal at least 30 days before the scheduled date of the meeting.

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.

Records related to the application may be examined at the White River National Forest, Supervisor's Office at 900 Grand Avenue, Glenwood Springs, Colorado 81601.

For a period until October 16, 2017, subject to valid existing rights, the lands described in this notice will be segregated from location and entry under the United States mining laws unless the application is denied or cancelled or the withdrawal is approved prior to that date. The lands will remain open to other uses within the statutory authority pertinent to National Forest System lands and subject to discretionary approval.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

(Authority: 43 CFR 2310.3–1(b))

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2015–26364 Filed 10–15–15; 8:45 am]

BILLING CODE 4311–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON05000 L16100000.DU0000]

Notice of Intent To Amend the Resource Management Plan for the White River Field Office and Prepare an Associated Environmental Assessment for Travel and Transportation Management, Colorado

AGENCY: Bureau of Land Management, Interior

ACTION: Notice.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA); and the Federal Land Policy and Management Act of 1976, as amended (FLPMA); the Bureau of Land Management (BLM) White River Field Office (WRFO), Meeker, Colorado, intends to prepare a

Resource Management Plan (RMP) amendment with an associated Environmental Assessment (EA) for the WRFO. By this notice the WRFO is announcing the beginning of the scoping process to solicit public comments and identify issues.

DATES: Comments on issues may be submitted in writing until November 16, 2015. The BLM will announce the date(s) and location(s) of any scoping meetings at least 15 days in advance through local news media, newspapers and the BLM Web site at: <http://www.blm.gov/co/st/en/fo/wrfo.html>. The BLM must receive all comments prior to the close of the 30-day scoping period or 15 days after the last public meeting, whichever is later, in order for them to be included in the analysis. We will provide additional opportunities for public participation as appropriate.

ADDRESSES: You may submit comments on issues and planning criteria related to the WRFO's Travel and Transportation Management RMP amendment/EA by any of the following methods:

- *Web site:* <http://www.blm.gov/co/st/en/fo/wrfo.html>.
- *Email:* blm_co_wrfo_tmp@blm.gov.
- *Fax:* 970–989–3805.
- *Mail:* BLM, White River Field Office, 220 East Market St., Meeker, CO 81641.

Documents pertinent to this proposal may be examined at the White River FO.

FOR FURTHER INFORMATION CONTACT:

Heather Sauls, Planning and Environmental Coordinator; telephone 970–878–3855; address White River FO (see address above); email hsauls@blm.gov. Contact Ms. Sauls to have your name added to our mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This document provides notice that the WRFO, Meeker, Colorado, intends to prepare an RMP amendment with an associated EA for the White River Planning Area, announces the beginning of the scoping process, and seeks public input on issues and planning criteria. The RMP amendment will address comprehensive transportation and travel management planning and will amend the 1997 WRFO RMP. At a minimum, the RMP amendment will consider designation of all public lands within

the planning area as “open areas” for off-road vehicle use, “limited areas” for off-road vehicle use, or “closed areas” to off-road vehicle use. The RMP amendment will also consider whether to further restrict other modes of transport (e.g., mechanized and non-motorized) through area allocations and allowable use decisions. The BLM will also address whether or not exceptions should be granted within closed or limited areas and provide general direction for how to address resource conflicts during future implementation-level planning. The planning area is located in Rio Blanco, Moffat and Garfield counties, Colorado, and encompasses approximately 1.5 million acres of public land.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the planning process. BLM personnel; Federal, State and local agencies; and other stakeholders identified the following preliminary issues for the RMP amendment area:

- Is there a recreational need for an open area?
- Are there areas that should be managed with seasonal closures on motorized vehicle use to allow for non-motorized hunting experiences?
- Should the White River FO provide exceptions for off-road motorized travel in limited areas for the purposes of camping, firewood gathering, or retrieval of downed big game?
- Should the WRFO provide exceptions for physically challenged individuals to travel off-road?
- Should the WRFO limit motorized over-the-snow travel by vehicle type, season, snow-depth, or other conditions?
- Should Pike Ridge be managed as closed to motorized vehicles?
- Should travel on existing energy and mineral development access roads be restricted to authorized use?
- Should right-of-way exclusion areas also be managed as closed areas?
- What types of uses are appropriate (e.g., motorized, mechanized, horseback) within right-of-way avoidance and exclusion areas?
- Should the WRFO implement seasonal or permanent road or trail closures in Greater Sage-Grouse habitat?
- Should construction of new roads be allowed within lands with wilderness characteristics?
- What types of uses are appropriate (e.g., motorized, mechanized, horseback) within lands with wilderness characteristics?

Preliminary Planning Criteria Include

1. The RMP amendment will be limited to making land use planning decisions specific to transportation and travel management.

2. The BLM will designate all public lands within the planning area as open, limited, or closed areas to off-road vehicle use.

3. Lands addressed in the RMP amendment will be surface lands managed by the BLM and will not include split-estate lands (*i.e.*, private surface with Federal mineral estate).

4. The RMP amendment, if approved, will comply with FLPMA, NEPA, Council on Environmental Quality regulations at 40 CFR 1500–1508, Department of the Interior regulations at 43 CFR 46 and 43 CFR 1600, the BLM Land Use Planning Handbook (H–1601–1), the BLM NEPA Handbook (H–1790–1), the BLM Travel and Transportation Management Handbook (H–8342–1), and all other applicable laws and BLM policies and guidance.

5. Land use decisions in Greater Sage-Grouse habitat considered in the RMP amendment will be consistent with land use decisions in the Northwest Colorado Greater Sage-Grouse RMP amendment.

6. The RMP amendment will recognize valid existing rights.

7. The BLM will use a collaborative approach to planning.

8. The BLM will consult with Indian tribes to identify sites, areas and objectives important to their cultural and religious heritage.

9. The BLM will coordinate and communicate with State, local and tribal governments to ensure the BLM considers provisions of pertinent plans; seek to resolve inconsistencies between State, local and tribal plans; and provide ample opportunities for State, local and tribal governments to comment on the development of the amendment.

10. The BLM will address socioeconomic and Environmental Justice impacts of the alternatives.

11. Land use allocations made for Wilderness Study Areas (WSA) must be consistent with the BLM Management of WSA manual (BLM Manual 6330) and with other laws, regulations and policies related to WSA management.

12. The BLM will consider public welfare and safety when addressing fire management in the context of travel and transportation management planning.

13. The BLM will not consider creating any new special designations, such as Areas of Critical Environmental Concern, through this RMP amendment.

14. The BLM will conduct implementation (route-by-route designations) travel management

planning in a separate effort subsequent to completing this RMP amendment.

You may submit comments on issues and planning criteria in writing to the BLM at any public scoping meeting, or you may submit them to the BLM using one of the methods listed in the

ADDRESSES section above. To be most helpful, you should submit comments by the close of the 30-day scoping period or within 15 days after the last public meeting, whichever is later.

The BLM will use the NEPA public participation requirements to assist in satisfying the public involvement requirements under Section 106 of the National Historic Preservation Act (NHPA) (16 U.S.C. 470(f)) pursuant to 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources in the context of both NEPA and Section 106 of the NHPA.

The BLM will consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. The BLM will give tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, due consideration. Federal, State and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed action the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency.

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.

The BLM will evaluate identified issues to be addressed in the plan, and will place them into one of three categories:

1. Issues to be resolved in the RMP amendment;
2. Issues to be resolved through policy or administrative action; or
3. Issues beyond the scope of this RMP amendment.

The BLM will provide an explanation in the Draft RMP amendment/preliminary EA as to why an issue was placed in category two or three. The BLM also encourages the public to help

identify any management questions and concerns that should be addressed in the plan. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns.

The BLM will use an interdisciplinary approach to develop the plan amendment in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process: Rangeland management, vegetation, riparian and wetlands, invasive and noxious weeds, minerals and geology, forestry, outdoor recreation, visual resource management, cultural resources and Native American concerns, paleontology, wildlife and fisheries, threatened and endangered species, lands and realty, hydrology, soils, wild horses, fire ecology and management, sociology and economics, public safety, law enforcement, and geographic information systems.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2015–26370 Filed 10–15–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLES962000 L14200000.B0000 15X]

Eastern States: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey; Wisconsin.

SUMMARY: The Bureau of Land Management (BLM) will officially file the plats of survey of the lands described below in the BLM-Eastern States Office, Washington, DC at least 30 calendar days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Eastern States Office, 20 M Street SE., Washington, DC 20003. Attn: Cadastral Survey. 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: These surveys were requested by the Bureau of Indian Affairs.

The lands surveyed are:

Fourth Principal Meridian, Wisconsin

T. 30 N., R. 16 E.

The plat of survey represents the Dependent Resurvey of a portion of the south boundary, a portion of the subdivisional lines, and a portion of the certified survey map recorded on Page 149, volume 2, in section 26, the retracement of a portion of the eastern right of way of county road "AA" in section 35, the survey of the subdivision of sections 25, 26, 35, and 36 and the western boundary of document No. 310, recorded on Page 31, volume 3, in section 35, and the informational traverse of the northern shore and a portion of the eastern shore of Vejo Lake in section 35 in Township 30 North, Range 16 East, of the 4th Principal Meridian, in the State of Wisconsin, and was accepted September 16, 2015.

Fourth Principal Meridian, Wisconsin

T. 51 N., R. 3 W.

The plat of survey represents the retracement of a portion of Blocks 4 and 5 of Buffalo's Subdivision and the retracement, resurvey and monumentation of specified lot and block corners and right of way intersection points, in Blocks 1, 2, and 3 of Buffalo's Subdivision, lands held in trust for the Red Cliff Band of Lake Superior Chippewa Indians in Government Lot 3, Section 31 of Township 51 North, Range 3 West, 4th Principle Meridian, in the State of Wisconsin, and was accepted September 1, 2015.

We will place a copy of the plats we described in the open files. They will be available to the public as a matter of information.

If BLM receives a protest against these surveys, as shown on the plats, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plats until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: October 7, 2015.

Dominica VanKoten,

Chief Cadastral Surveyor.

[FR Doc. 2015-26402 Filed 10-15-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO923000 L14400000.FR0000]

Initial Classification of Public Lands and Minerals for State Indemnity Selection, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Colorado State Board of Land Commissioners (State) has filed a petition for classification and application to obtain public lands and mineral estate in lieu of lands to which the State was entitled but did not receive under its Statehood Act. The State did not receive title because the lands had been included in an Indian Reservation, Forest Reserve, National Forest, or other encumbrance at the time of statehood. Under the Taylor Grazing Act of 1934, the Bureau of Land Management (BLM) may classify sufficient public lands and/or minerals in Colorado for title transfer to the State to satisfy this obligation.

DATES: Interested parties may submit written comments regarding the classification of lands and minerals on or before November 16, 2015. Persons asserting a claim to or interest in the lands or mineral estate described in this notice will find the requirements for filing such claims in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Written comments concerning this Notice should be addressed to: State Director, Bureau of Land Management, Colorado State Office, 2850 Youngfield Street, Lakewood, CO 80215-7093.

FOR FURTHER INFORMATION CONTACT: John D. Beck, Chief, Branch of Lands and Realty; telephone 303-239-3882; email jbeck@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: Sections 2275 and 2276 of the Revised Statutes, as amended (43 U.S.C. 851 and 852), provide authority for Colorado to receive title to public lands in lieu of lands to which it was entitled under Section 7 of its statehood act of March 3, 1875, where it did not receive title because those lands had otherwise been encumbered.

Section 7 of the Taylor Grazing Act of June 8, 1934, clarified by the Supreme Court in *Andrus v. Utah*, 446 U.S. 500 (1980), requires that such public lands and/or minerals identified for proposed transfers out of Federal ownership under this authority must first be classified. The BLM is classifying these lands and minerals pursuant to 43 CFR 2400 and Section 7 of the Act of June 8, 1934 (48 Stat. 1272, as amended), 43 U.S.C. 315(f). The final acres conveyed will be determined after further environmental analysis is completed, will be based on a dollar value, and may be less than the aggregate acreage described in this notice.

All persons who wish to submit comments on a motion of any protestant with this initial classification may present their views by any means shown under the **ADDRESSES** section above.

The BLM Colorado State Director will evaluate any adverse comment and issue a notice of determination to proceed with, modify, or cancel the proposed action. In the absence of any action by the BLM State Director, this initial classification action will become the final determination of the Department of the Interior.

The BLM will review any comments and may sustain, vacate, or modify this realty action. In the absence of any adverse comments, the classification of the land described in this notice will become effective on December 15, 2015.

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. As provided by 43 CFR 2462.1, the BLM Colorado State Director will schedule a public hearing. The BLM will announce the public hearing date 15 days prior to the hearing.

The lands and minerals included within this initial classification are in Chaffee, Custer, Dolores, Eagle, El Paso, Garfield, Grand, Huerfano, Jackson, Kiowa, La Plata, Moffat, Montezuma, Ouray, Park, Pueblo, Routt, San Miguel and Weld counties, Colorado, and are described as follows:

New Mexico Principle Meridian, Colorado

T. 44 N., R. 8 W.,

Sec. 11, lots 12 thru 14, excluding M.S. No. 9195;

Sec. 13, lots 17, 28, 30, and 31;

Sec. 14, E $\frac{1}{2}$ SE $\frac{1}{4}$.

T. 42 N., R. 13 W.,

Sec. 30, NE $\frac{1}{4}$ NE $\frac{1}{4}$.

- T. 40 N., R. 14 W.,
Sec. 6, lot 13 and NE $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 41 N., R. 14 W.,
Sec. 28, S $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 29, SW $\frac{1}{4}$, NE $\frac{1}{4}$ SE $\frac{1}{4}$, and S $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 30, N $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 31 N $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 32, N $\frac{1}{2}$ NW $\frac{1}{4}$ and SW $\frac{1}{4}$ NW $\frac{1}{4}$.
- T. 43 N., R. 14 W.,
Sec. 2, lots 1 and 2, and S $\frac{1}{2}$ NE $\frac{1}{4}$.
- T. 40 N., R. 15 W.,
Sec. 1, lots 1 thru 4;
Sec. 3, lots 3 and 4;
Sec. 4, lots 1 thru 4;
Sec. 10, N $\frac{1}{2}$ NE $\frac{1}{4}$ and E $\frac{1}{2}$ NW $\frac{1}{4}$;
Sec. 11, N $\frac{1}{2}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, and SW $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 50 N., R 8 E.,
Sec. 7, NE $\frac{1}{4}$ NE $\frac{1}{4}$.
- Sixth Principle Meridian, Colorado**
- T. 19 S., R. 45 W.,
Sec. 10, S $\frac{1}{2}$ NE $\frac{1}{4}$;
Sec. 11, SW $\frac{1}{4}$;
Sec. 14, N $\frac{1}{2}$ and SE $\frac{1}{4}$;
Sec. 15, NE $\frac{1}{4}$.
- T. 20 S., R. 47 W.,
Sec. 4, S $\frac{1}{2}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$, and W $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 5;
Sec. 8, NE $\frac{1}{4}$ NE $\frac{1}{4}$, W $\frac{1}{2}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ NE $\frac{1}{4}$,
NW $\frac{1}{4}$, NE $\frac{1}{4}$ SW $\frac{1}{4}$, and NW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 9, NE $\frac{1}{4}$, NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$,
and SE $\frac{1}{4}$;
Sec. 10, SW $\frac{1}{4}$ and SW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 15, NW $\frac{1}{4}$ NE $\frac{1}{4}$;
Sec. 22, SE $\frac{1}{4}$ NE $\frac{1}{4}$ and E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 23, S $\frac{1}{2}$ NW $\frac{1}{4}$ and SW $\frac{1}{4}$;
Sec. 26, W $\frac{1}{2}$ NE $\frac{1}{4}$, NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, and
NW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 27, NE $\frac{1}{4}$ NE $\frac{1}{4}$.
- T. 20 S., R. 48 W.,
Sec. 10, W $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 13, S $\frac{1}{2}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$, and W $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 14, SE $\frac{1}{4}$ SW $\frac{1}{4}$ and SE $\frac{1}{4}$;
Sec. 15, W $\frac{1}{2}$ NW $\frac{1}{4}$ and NW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 22, E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 23;
Sec. 24, NW $\frac{1}{4}$ NE $\frac{1}{4}$, NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, and
SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 26, NE $\frac{1}{4}$, NW $\frac{1}{4}$, and W $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 27, E $\frac{1}{2}$ NE $\frac{1}{4}$.
- T. 18 S., R. 61 W.,
Sec. 8, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 19, lots 3 and 4, E $\frac{1}{2}$ SW $\frac{1}{4}$, and SE $\frac{1}{4}$;
Sec. 30, lots 2 thru 4, SE $\frac{1}{4}$ NW $\frac{1}{4}$,
E $\frac{1}{2}$ SW $\frac{1}{4}$, and W $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 32.
- T. 19 S., R. 61 W.,
Sec. 6;
Sec. 7, E $\frac{1}{2}$ NE $\frac{1}{4}$ and E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 8, W $\frac{1}{2}$ NW $\frac{1}{4}$ and W $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 18;
Sec. 19, lots 1 thru 4, NE $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$, and
E $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 20;
Sec. 28, E $\frac{1}{2}$;
Sec. 29, W $\frac{1}{2}$;
Sec. 32, E $\frac{1}{2}$;
Sec. 33.
- T. 20 S., R. 61 W.,
Sec. 4;
Sec. 5, lots 1 and 2, S $\frac{1}{2}$ NE $\frac{1}{4}$, and SE $\frac{1}{4}$;
Sec. 7, lots 2 and 3, and SE $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 9, E $\frac{1}{2}$;
Sec. 18, SW $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 16 S., R. 62 W.,
Sec. 24, NW $\frac{1}{4}$ NW $\frac{1}{4}$.
- T. 17 S., R. 62 W.,
Sec. 1, lot 1 and SE $\frac{1}{4}$ NE $\frac{1}{4}$;
Sec. 9, SE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 29 S., R. 69 W.,
Sec. 31, lots 3 and 4, NE $\frac{1}{4}$ NE $\frac{1}{4}$,
NE $\frac{1}{4}$ NW $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$, and SE $\frac{1}{4}$;
Sec. 32, SW $\frac{1}{4}$ NW $\frac{1}{4}$, W $\frac{1}{2}$ SW $\frac{1}{4}$,
SE $\frac{1}{4}$ SW $\frac{1}{4}$, and SE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 29 S., R. 70 W.,
Sec. 35, lot 1.
- T. 22 S., R. 71 W.,
Sec. 5, lots 20 thru 23;
Sec. 6, lot 13;
Sec. 8, NW $\frac{1}{4}$ NW $\frac{1}{4}$;
Sec. 17, lot 24.
- T. 22 S., R. 72 W.,
Sec. 4, lots 41, 42, and 47, and NE $\frac{1}{4}$ SE $\frac{1}{4}$,
and remaining public lands in
SW $\frac{1}{4}$ NW $\frac{1}{4}$, W $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$, and
SW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 5, remaining public lands in S $\frac{1}{2}$ NE $\frac{1}{4}$,
SE $\frac{1}{4}$ NW $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$, and
NW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 8, remaining public lands in
SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 9, remaining public lands in W $\frac{1}{2}$;
Sec. 12, lot 3 and SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 16, lot 20, lots 23 thru 36, and lot 38;
Sec. 17, remaining public lands in
NW $\frac{1}{4}$ NE $\frac{1}{4}$;
Sec. 22, N $\frac{1}{2}$ NE $\frac{1}{4}$;
Sec. 26, SE $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 28, N $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$,
and SE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 11 S., R. 74 W.,
Sec. 20, NE $\frac{1}{4}$;
Sec. 21, W $\frac{1}{2}$.
- T. 12 S., R. 75 W.,
Sec. 17, SW $\frac{1}{4}$;
Sec. 18, lots 1 thru 4, E $\frac{1}{2}$ NW $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$,
and SE $\frac{1}{4}$;
Sec. 19, lots 1 and 2, N $\frac{1}{2}$ NE $\frac{1}{4}$, SW $\frac{1}{4}$ NE $\frac{1}{4}$,
and E $\frac{1}{2}$ NW $\frac{1}{4}$.
- T. 12 S., R. 76 W.,
Sec. 13, E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 24, NE $\frac{1}{4}$.
- T. 13 S., R. 76 W.,
Sec. 4, lots 2 thru 4, SW $\frac{1}{4}$ NW $\frac{1}{4}$, and
NW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 5;
Sec. 6, lots 6 and 7, and E $\frac{1}{2}$ SW $\frac{1}{4}$.
- T. 12 S., R. 77 W.,
Sec. 23, N $\frac{1}{2}$ SW $\frac{1}{4}$ and N $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 25, S $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 34, NW $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 15 S., R. 78 W.,
Sec. 17, SW $\frac{1}{4}$ NW $\frac{1}{4}$, including geothermal
steam;
Sec. 18, N $\frac{1}{2}$ SE $\frac{1}{4}$ and SW $\frac{1}{4}$ SE $\frac{1}{4}$,
including geothermal steam.
- T. 4 S., R. 83 W.,
Sec. 17, lots 2 and 5, NE $\frac{1}{4}$ SW $\frac{1}{4}$, and
NW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 22, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 23, lots 6 thru 8, and W $\frac{1}{2}$ SW $\frac{1}{4}$.
- T. 7 S., R. 88 W.,
Sec. 7, lots 12 and 13;
Sec. 8, lot 7, SW $\frac{1}{4}$ NE $\frac{1}{4}$, and SE $\frac{1}{4}$ NW $\frac{1}{4}$;
Sec. 17, lots 3 and 19.
- T. 7 S., R. 89 W.,
Sec. 3, lot 1, SE $\frac{1}{4}$ NE $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$,
E $\frac{1}{2}$ W $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$, and E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 12, lot 22 and W $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 13, NW $\frac{1}{4}$;
T. 5 S., R. 92 W.,
Sec. 30, W $\frac{1}{2}$ SE $\frac{1}{4}$.
- T. 5 S., R. 93 W.,
Sec. 36, NW $\frac{1}{4}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ NW $\frac{1}{4}$, and
NE $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 1 N, R. 76 $\frac{1}{2}$ W.,
Sec. 1, lots 15 and 16;
Sec. 12, lots 1 thru 6, and lots 11 and 12.
- T. 1 N., R. 77 W.,
Sec. 12, E $\frac{1}{2}$ NE $\frac{1}{4}$ and NE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 3 N., R. 77 W.,
Sec. 25, S $\frac{1}{2}$ SW $\frac{1}{4}$ and SW $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 4 N., R. 81 W.,
Sec. 34, W $\frac{1}{2}$ NW $\frac{1}{4}$ and NW $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 6 N., R. 81 W.,
Sec. 18, lot 5.
- T. 3 N., R. 82 W.,
Sec. 26, lot 1.
- T. 6 N., R. 82 W.,
Sec. 13, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 23, N $\frac{1}{2}$ NE $\frac{1}{4}$ and SE $\frac{1}{4}$ NE $\frac{1}{4}$.
- T. 6 N., R. 84 W.,
Sec. 27, SE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 7 N., R. 85 W.,
Sec. 17, W $\frac{1}{2}$ NE $\frac{1}{4}$.
- T. 8 N., R. 85 W.,
Sec. 16, lots 4 and 5.
- T. 6 N., R. 86 W.,
Sec. 33, SW $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 7 N., R. 88 W.,
Sec. 2, SE $\frac{1}{4}$ NW $\frac{1}{4}$.
- T. 8 N., R. 88 W.,
Sec. 34, lots 12 thru 15.
- T. 7 N., R. 93 W.,
Sec. 36.
The areas described aggregate 23,077 acres.
- The State's application requests
conveyance of title to Federal
mineral estate under surface owned
by the State, described as follows:
- Sixth Principle Meridian, Colorado**
- T. 9 N., R. 56 W.,
Sec. 24, SW $\frac{1}{4}$.
- T. 12 N., R. 56 W.,
Sec. 28, E $\frac{1}{2}$.
- T. 11 N., R. 59 W.,
Sec. 15, NE $\frac{1}{4}$.
- T. 5 N., R. 61 W.,
Sec. 33, SW $\frac{1}{4}$.
- T. 3 N., R. 62 W.,
Sec. 1, SE $\frac{1}{4}$.
- T. 17 S., R. 48 W.,
Sec. 18, NW $\frac{1}{4}$ NE $\frac{1}{4}$.
- T. 21 S., R. 51 W.,
Sec. 35, NW $\frac{1}{4}$ SW $\frac{1}{4}$ (oil and gas only).
- T. 22 S., R. 52 W.,
Sec. 15, SW $\frac{1}{4}$ NE $\frac{1}{4}$, NW $\frac{1}{4}$ SW $\frac{1}{4}$, and
NW $\frac{1}{4}$ SE $\frac{1}{4}$ (oil and gas only).
- T. 28 S., R. 69 W.,
Sec. 17, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 20, NE $\frac{1}{4}$ and NE $\frac{1}{4}$ NW $\frac{1}{4}$;
Sec. 21, NE $\frac{1}{4}$, W $\frac{1}{2}$ NW $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$, and
NE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 22, W $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$, and
SW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 27, NW $\frac{1}{4}$ NE $\frac{1}{4}$ and NE $\frac{1}{4}$ NW $\frac{1}{4}$.
- T. 6 N., R. 79 W.,
Sec. 3, SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 4, lots 3 and 4, SW $\frac{1}{4}$ NE $\frac{1}{4}$, S $\frac{1}{2}$ NW $\frac{1}{4}$,
SW $\frac{1}{4}$, and SE $\frac{1}{4}$;
Sec. 5, lots 1 and 2, S $\frac{1}{2}$ NE $\frac{1}{4}$, and SE $\frac{1}{4}$;
Sec. 8, N $\frac{1}{2}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ NE $\frac{1}{4}$, and E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 9;
Sec. 10, W $\frac{1}{2}$ NW $\frac{1}{4}$ and W $\frac{1}{2}$ SW $\frac{1}{4}$.
- T. 7 N., R. 79 W.,
Sec. 32, SE $\frac{1}{4}$;

Sec. 33, W $\frac{1}{2}$ SW $\frac{1}{4}$.
 T. 5 N., R. 88 W.,
 Sec. 12, NW $\frac{1}{4}$ and SW $\frac{1}{4}$.
 T. 7 N., R. 88 W.,
 Sec. 1, SW $\frac{1}{4}$ NW $\frac{1}{4}$, W $\frac{1}{2}$ SW $\frac{1}{4}$, and
 SE $\frac{1}{4}$ SW $\frac{1}{4}$, and those portions of
 SE $\frac{1}{4}$ NW $\frac{1}{4}$, NE $\frac{1}{4}$ SW $\frac{1}{4}$, NW $\frac{1}{4}$ SE $\frac{1}{4}$, and
 SW $\frac{1}{4}$ SE $\frac{1}{4}$ lying west of Routt County
 Road 80A;
 Sec. 2, S $\frac{1}{2}$ NE $\frac{1}{4}$ and SE $\frac{1}{4}$;
 Sec. 10, NE $\frac{1}{4}$ and NW $\frac{1}{4}$;
 Sec. 11, N $\frac{1}{2}$ and SE $\frac{1}{4}$;
 Sec. 12, those portions of W $\frac{1}{2}$ lying west
 of Routt County Road 80.
 The areas described aggregate 6,354 acres.

If and when the selection is approved and certified to the State, the Clear List may either be subject to or reserve any rights-of-way granted by the BLM. Oil and gas, geothermal, or other leases issued under the authority of the Mineral Leasing Act of 1920 (30 U.S.C 181 *et seq.*) will remain in effect under the terms and conditions of the leases. Pursuant to 43 CFR 2462.2, publication of this notice of initial classification in the **Federal Register** segregates the above described lands from all forms of disposal under the public land laws, including the mining laws, except for the form of land disposal specified in this notice of initial classification. However, this notice does not alter the applicability of the public land laws governing the use of the lands under lease, license, or permit, or governing the disposal of their mineral and vegetative resources, other than under the mining laws.

The segregative effect of a classification for this form of disposal will terminate in one of the following ways:

- (1) Disposal of the lands.
- (2) Publication in the **Federal Register** of a notice of termination of the classification.
- (3) An Act of Congress.

Authority: 43 CFR 2400.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2015-26365 Filed 10-15-15; 8:45 am]

BILLING CODE 4310-JB-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-19126;
 PPWOCRADN0-PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, National Park Service, Natchez Trace Parkway, Tupelo, MS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, National Park Service, Natchez Trace Parkway has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian tribes or Native Hawaiian organizations. Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Natchez Trace Parkway. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Natchez Trace Parkway at the address in this notice by November 16, 2015.

ADDRESSES: Mary Risser, Superintendent, Natchez Trace Parkway, 2680 Natchez Trace Parkway, Tupelo, MS 38804-9715, telephone (662) 680-4005, email mary_risser@nps.gov.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the U.S. Department of the Interior, National Park Service, Natchez Trace Parkway, Tupelo, MS. The human remains and associated funerary objects were removed from Lee, Prentiss, and Tishomingo Counties, MS.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the Superintendent, Natchez Trace Parkway.

Consultation

A detailed assessment of the human remains was made by Natchez Trace Parkway professional staff in consultation with representatives of the

Alabama-Coushatta Tribe of Texas, The Chickasaw Nation, and the United Keetoowah Band of Cherokee Indians in Oklahoma.

History and Description of the Remains

On an unknown date, human remains representing, at minimum, three individuals, were removed from the Citizens Bank Property site in Lee County, MS. The exact details of removal are unknown, but documentation indicates that the remains were likely removed by Natchez Trace naturalist Francis Elmore. No known individuals were identified. No associated funerary objects are present.

In 1940, human remains representing, at minimum, four individuals were removed from the Carr site in Lee County, MS, during Works Progress Administration (WPA) excavations. The site is dated to the Late Woodland-Early Mississippian period (circa 1000 B.C.–A.D. 1200). No known individuals were identified. The 287 associated funerary objects are 140 Mulberry Creek vessel fragments, 3 Furrs Cord Marked vessel fragments, 1 Mississippi Plain vessel fragment, 8 Baytown Plain vessel fragments, 1 Baldwin Plain vessel fragment, 6 untyped vessel fragments, 1 piece of daub, 5 flakes, 3 pieces of shatter, 1 piece of ochre, 2 flake tools, 1 scraper, 2 bifaces, 1 core tool, 2 pieces of sandstone, 29 deer bones, 1 turkey bone, 6 box turtle bones, 26 mammal bones, and 48 animal bones.

In 1940, human remains representing, at minimum, one individual were removed from Jennings Dig Number One in Lee County, MS, during WPA excavations. The site is dated to the Miller I–II periods (100 B.C.–A.D. 500). No known individuals were identified. The 22 associated funerary objects are 1 biface, 1 piece of shatter, 1 concretion, 3 Baytown Plain vessel fragments, 1 untyped vessel fragment, and 15 fossil fragments.

In 1940, human remains representing, at minimum, 35 individuals were removed from Miller Mounds in Lee County, MS, during WPA excavations. The site is dated to the Woodland period (A.D. 500–1000). No known individuals were identified. The 39 associated funerary objects are 4 Saltillo Fabric Marked vessel fragments, 3 Saltillo Plain vessel fragments, 2 Baldwin Plain vessel fragments, 5 untyped vessel fragments, 7 projectile points, 1 Lowe Cluster projectile point, 3 bifaces, 4 flakes, 1 platform pipe, 1 busycon shell, 1 chert knife, 1 piece of shatter, 1 unmodified stone, 2 flake tools, 2 Baldwin Plain bowls, and 1 Furrs Cord Marked jar.

In 1947–1951, human remains representing, at minimum, one individual were removed from the Chewapa site in Lee County, MS, by an unknown individual who gave the remains to the WPA survey in the area. The site is dated to the Miller III/Late Woodland period (circa A.D. 500–1200). No known individuals were identified. No associated funerary objects are present.

In 1948, human remains representing, at minimum, one individual were removed from Headquarters Mound in Lee County, MS, during excavation and survey. The site dates to the Late Woodland period (circa A.D. 500–1000). No known individuals were identified. No associated funerary objects are present.

In 1948, human remains representing, at minimum, three individuals were removed from Old Rodgers Place Number One in Lee County, MS, during a WPA survey. The site is prehistoric Native American, but an exact date is unknown. No known individuals were identified. No associated funerary objects are present.

In 1949, human remains representing, at minimum, one individual, were removed from the Coonewah Creek site in Lee County, MS, during a site survey. The site dates to the Miller III/Late Woodland Period (circa A.D. 500–1200). No known individuals were identified. No associated funerary objects are present.

In 1965, human remains representing, at minimum, three individuals were removed from Bear Creek Temple Mound in Tishomingo County, MS, during archeological investigations. The site dates to the Late Mississippian period (circa A.D. 1400–1600). No known individuals were identified. The three associated funerary objects are one untyped vessel fragment and two deer bones.

In 1972, human remains representing, at minimum, six individuals were removed from Pharr Mounds in Prentiss County, MS, during excavations of the village area and four mounds. The site dates to the Miller I–II phases of the Middle Woodland period (circa A.D. 0–500). No known individuals were identified. The 14 associated funerary objects are 7 Saltillo Fabric vessel fragments, 6 Baldwin Plain vessel fragments, and 1 untyped vessel fragment.

In 1978, human remains representing, at minimum, two individuals were removed from Pharr Mounds in Prentiss County, MS. The remains were removed during excavations to investigate the impact of construction near the site. No

known individuals were identified. No associated funerary objects are present.

Cultural affiliation of the human remains described above could not be determined due to uncertain burial provenience, lack of culturally affiliated historic artifacts, and/or the antiquity of the remains.

Determinations Made by Natchez Trace Parkway

Officials of Natchez Trace Parkway have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on archeological context.

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 60 individuals of Native American ancestry.

- Pursuant to 25 U.S.C. 3001(3)(A), the 365 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. The National Park Service intends to convey the associated funerary objects to the tribes pursuant to 16 U.S.C. 18f–2.

- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian tribe.

- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of The Chickasaw Nation.

- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to The Chickasaw Nation.

Additional Requestors and Disposition

Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Mary Risser, Superintendent, Natchez Trace Parkway, 2680 Natchez Trace Parkway, Tupelo, MS 38804–9715, telephone (662) 680–4005, email mary_risser@nps.gov, by November 16, 2015. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Chickasaw Nation may proceed.

Natchez Trace Parkway is responsible for notifying the Alabama-Coushatta Tribe of Texas, The Chickasaw Nation,

and the United Keetoowah Band of Cherokee Indians in Oklahoma that this notice has been published.

Dated: August 25, 2015.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2015–26331 Filed 10–15–15; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Number 1010—New; MMAA104000]

Information Collection: Atlantic Offshore Wind Energy Development—Public Attitudes, Values, and Implications for Tourism and Recreation; Submitted for OMB Review; Comment Request

ACTION: 30-day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Ocean Energy Management (BOEM) is notifying the public that we have submitted an information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval. The ICR concerns a new survey on the potential impacts of Atlantic offshore wind energy development on coastal tourism and recreation. This notice provides the public a second opportunity to comment on the paperwork burden of this collection.

DATES: Submit written comments by November 16, 2015.

ADDRESSES: Submit comments on this ICR 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 BOEM Information Collection Clearance Officer, Kye Mason, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166 (mail) or kye.mason@boem.gov (email). Please reference ICR 1010–New in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Kye Mason, Office of Policy, Regulations, and Analysis at kye.mason@boem.gov (email) or (703) 787–1025 (phone). 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: 1010—New.

Title: Atlantic Offshore Wind Energy Development: Public Attitudes, Values,

and Implications for Tourism and Recreation.

Abstract: Under the Outer Continental Shelf (OCS) Lands Act (43 U.S.C. 1331–1356), BOEM is responsible for conducting OCS lease sales and for monitoring and mitigating adverse impacts that might be associated with offshore energy development. The Energy Policy Act of 2005 (42 U.S.C. 13201 *et seq.*) authorizes the Secretary of the Interior to issue leases, easements, and rights-of-way for offshore renewable energy activities in Federal waters, such as offshore wind power development. In fulfilling these responsibilities, BOEM must take into consideration the impacts of OCS activities on recreational resources. While we have seen significant interest in offshore wind power development in recent years, the absence of baseline data for

specific areas along the Atlantic coast and the absence of a broader regional study on tourism and wind power have made it difficult to identify and analyze the potential impacts of offshore wind development on coastal tourism and recreation. Additional information on these potential impacts will contribute to better planning and decision making for BOEM and other stakeholders, including other Federal agencies and State and local governments.

Under a cooperative agreement awarded by the Department of the Interior, the University of Delaware will conduct a survey to assess the impact of offshore wind power projects on coastal recreation and tourism from Massachusetts to South Carolina. The survey will gauge public perceptions of offshore wind energy projects and how development could impact future

recreation and visitation choices. BOEM will use this information, along with other economic and environmental information, in our offshore wind decision making process and marine spatial planning efforts. States and coastal communities will use the information for local coastal planning efforts.

The data collection will be done by an Internet-based survey. We decided to use an internet-based approach in part to improve the images respondents are shown. The internet also allows us to easily accommodate different skip patterns and variation in wind projects shown to respondents.

Frequency: One time.

Description of Respondents: Individuals.

TOTAL ANNUAL BURDEN HOURS

Activity	Annual number of responses	Average completion time per person (minutes)	Total annual burden hours
General Population Sample			
Non-respondents & Dropouts	88	2	3
Respondents	500	15	125
Total	588	17	128
Beachgoer-Only Sample			
Non-respondents & Dropouts	3,778	3	189
Respondents	1,600	15	400
Total	5,378	18	589
Overall Total	5,966	717

Estimated Reporting and Recordkeeping Non-hour Cost Burden: We have not identified any non-hour cost burdens for 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: We 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 burden estimates;

- Ways to enhance the quality, utility, and clarity of the information to be collected; and

- Ways to minimize the burden on respondents.

To comply with the public consultation process, on July 1, 2014, BOEM published a **Federal Register** notice (79 FR 37348) announcing that we would submit this ICR to OMB for approval. This notice provided the required 60-day comment period. We received comments from one person.

Comment: The location of residence (primary or secondary) should be given as a zip code. The zip code then determines the city, State, and distance to beach. There is no need for the respondent to guess what the distance is.

Response: The distance question has been deleted.

Comment: Offshore wind farms is a mature technology. A simple google image search shows a variety of real photos of wind farms off Denmark and the UK. Consider the use of real pictures in place of simulated offshore wind turbines.

Response: We are particularly interested in the impact on beach use and tourism of wind projects at different distances offshore. It is not feasible to find pictures of existing projects at different distances while keeping other features constant (*e.g.*, number of turbines, size of turbines, beach appearance, production quality for presentation on the Internet, etc.). The simulations allow us to “move wind projects” to different distances holding all other features constant. We also are interested in specific turbine sizes (larger than most of the existing ones) and turbine numbers (also larger than

most existing projects). We also want to use beaches on the Atlantic coast for our shots. The coastlines in Europe where turbines exist are very different from the coastline in the United States.

Comment: The geology of the Atlantic OCS indicates it is a natural gas province. For example in the 1970s, there was a natural gas discovery off the coast of Atlantic City, New Jersey. Natural gas production accidents do not yield oil and tar balls. A better hypothetical would be beach closures from hurricanes and nor'easters. The respondents should be familiar with these kinds of events.

Response: These hypothetical beach closure questions have been dropped altogether.

Comment: There is a question asking for personal annual income from working. There are many who have considerable income without working. Is it the intent not to capture this information? They have the time and the resources to be frequent ocean beach users.

Response: The income question has been changed to read: "Which category is closest to your personal annual income before taxes?"

Comment: The stratum sample sizes for the survey gives the appearance of being arbitrary. Consider that New Jersey & Delaware has a stratum of population of 8.8 million with a sample size of 200 participants. That works out to 22.73 participants per million. Compare to Pennsylvania 10.4 million population with 150 participants which is 14.42 participants per million. So citizens of Delaware are about 50% more likely to be selected as compared to Pennsylvania citizens. For full disclosure the University of Delaware is conducting the survey and I am a resident of Pennsylvania who is also a property owner in New Jersey. Further someone in Memphis, TN, is part of the survey universe, however someone living in Vermont is excluded. I have family members who live in Vermont and frequently visit the Jersey Shore.

Response: Based on this comment and comments from others we have redesigned the sampling strategy to include two separate samples: A General Population Sample and an Oversample Sample. The former is a random draw from all individuals in the 20 states in our region (now including Vermont, New Hampshire, Maine, and Georgia) and the latter is a random draw from all beachgoers in the same states. Since both of these samples are randomly drawn, the representation is proportional to state populations.

Comment: A good property of selected stratum is to have homogeneity within

the stratum (http://en.wikipedia.org/wiki/Stratified_sampling). The use of New York state as a stratum fails this principal. There is Long Island which is the beach community. New York City a major city with near by ocean beaches. Up state New York has ocean beaches which are more distant. Does not make sense to put Hampton's and Buffalo in the same stratum!

Response: See comment to previous question. We no longer stratify by state.

Comment: The total sample size for the participants of 1,400 is reasonable for obtaining summary insights. The data collection includes attributes, such as distance to the beach, education, number of children, employment status and income. If this survey has a goal of obtaining insights at this kind of granular level then the sample size will need to be adjusted to meet these goals.

Response: Our budget limits us to the sample size we are using.

Comment: The statistical survey design should follow Dillman's Tailored Design Method (http://www.amazon.com/Internet-Phone-Mail-Mixed-Mode-Surveys/dp/1118456149/ref=dp_ob_title_bk). This is the approach that is being used by BOEM in Alaska in the Arctic Communities Survey.

Response: Our survey follows Dillman's method fairly closely. It may depart in a few instances based on our own judgment calls, but it is largely based on Dillman.

Comment: The commenter made the following recommendations:

- Establish clear goals for the information collection, which then drives the design.
- Use Dillman's Tailored Design Method.
- Create strata that are approximately homogeneous. Suggested strata: Near Ocean Beaches (SC coast, Outer Banks, Tidewater VA, Delmarva, Jersey shore, Long Island, Rhode Island, Cape Cod), Metro Areas (Washington, Baltimore, Philadelphia, New York City, Boston metro areas), Inland (Other parts of SC, NC, VA, MD, Central PA, NJ, CT, MA), Distant Areas (OH, WV, TN, KY, Western PA, Upstate NY, VT, NH).
- Use zip codes for location of respondents.
- Publish the raw data so it can be independently analyzed.

Response: We addressed most of the recommendations in our responses. As noted, our survey was designed with a specific economic model in mind—a travel cost model; we use Dillman's approach fairly closely, but not always; we no longer stratify by geography; and we will use zip codes for location of the

respondents. In addition, we plan to publish the raw data.

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: October 1, 2015.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulations, and Analysis.

[FR Doc. 2015-25971 Filed 10-15-15; 8:45 am]

BILLING CODE 4310-MR-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-956]

Certain Recombinant Factor VIII Products; Commission Determination Not To Review an Initial Determination Granting an Unopposed Motion To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 10) granting an unopposed motion to add as complainants Baxalta, Inc. of Deerfield, Illinois; Baxalta US Inc. of Deerfield, Illinois; and Baxalta GmbH of Glattpark, Switzerland.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired

persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 22, 2015, based on a complaint filed by Baxter International Inc. of Deerfield, Illinois; Baxter Healthcare Corporation of Deerfield, Illinois; and Baxter Healthcare SA of Glattpark, Switzerland ("Baxter"). 80 FR 29745 (May 22, 2015). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain recombinant factor VIII products by reason of infringement of certain claims of U.S. Patent Nos. 6,100,061; 6,936,441; and 8,084,252. *Id.* The notice of investigation named Novo Nordisk A/S of Bagsvaerd, Denmark and Novo Nordisk Inc. of Plainsboro, New Jersey ("Novo Nordisk") as respondents. *Id.* at 29746. The Office of Unfair Import Investigations ("OUII") also was named as a party to the investigation. *Id.*

On September 3, 2015, Baxter filed a motion to amend the complaint and notice of investigation to add Baxalta, Inc., Baxalta US Inc., and Baxalta GmbH ("the Baxalta entities") as complainants. Neither Novo Nordisk nor OUII opposed the motion.

On September 16, 2015, the presiding administrative law judge ("ALJ") issued an ID, Order No. 10, granting the motion to amend the complaint and notice of investigation. The ALJ found good cause for the amendment. The ALJ found the amendment would not prejudice the parties because (1) they have been aware of a corporate transition involving Baxter and the Baxalta entities since the service of the complaint and the notice of investigation and (2) Baxter has been responding to discovery requests as though they were directed to Baxter and the Baxalta entities and will continue to do so. The ALJ found that having the correct parties in the investigation would simplify and streamline the discovery process. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 8, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015-26295 Filed 10-15-15; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-958]

Certain Automated Teller Machines and Point of Sale Devices and Associated Software Thereof; Notice of Commission Determination Not To Review an Initial Determination Granting Complainant's Motion To Amend the Complaint and the Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 9) issued by the presiding administrative law judge ("ALJ"), granting the complainant's unopposed motion to amend the complaint and notice of investigation to change the corporate name of the complainant.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 9, 2015, based on a complaint filed by Global Cash Access, Inc. ("Complainant"). 80 FR 32605-06. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), in the importation into the

United States, the sale for importation, and the sale within the United States after importation of certain automated teller machines, point of sale devices, and associated software that infringes claims 1-3, 5-7, and 9 of U.S. Patent No. 6,081,792. *Id.* The Commission's notice of investigation named as respondents NRT Technology Corp. of Toronto, Canada and NRT Technologies, Inc., of Las Vegas, Nevada. *Id.* at 32606. The Office of Unfair Import Investigations (OUII) is a party to the investigation. *Id.*

On August 26, 2015, Complainant filed an unopposed motion to amend the complaint and the notice of investigation to change the name of Complainant to Everi Payments Inc. to reflect a corporate name change. Complainant asserts that good cause exists for the amendments.

On September 15, 2015, the ALJ issued the subject ID, granting Complainant's motion to amend the complaint and the notice of investigation. The ALJ found good cause for granting the motion because it is early in the investigation and the amendments will not affect discovery or any issue to be litigated. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 9, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015-26307 Filed 10-15-15; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1110-0058]

Agency Information Collection Activities: Proposed eCollection, eComments Requested; Revision of a Currently Approved Collection; National Incident-Based Reporting System (NIBRS)

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division has submitted the following information collection request to the

Office of Management and Budget (OMB) for review and clearance in accordance with established review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** 80 *FR* 48567, on August 13, 2015, allowing for a 60 day comment period.

DATES: The purpose of this notice is to allow for an additional 30 days for public comment until November 16, 2015.

FOR FURTHER INFORMATION CONTACT:

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Mr. Samuel Berhanu, Unit Chief, Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, Module E-3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; facsimile (304) 625-3566. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to OIRA_submissions@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *The Title of the Form/Collection:* National Incident-Based Reporting System

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number: 1110-0058 Sponsor: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: City, county, state, tribal, and federal law enforcement agencies.

Abstract: Under U.S. Code, Title 28, Section 534, Acquisition, Preservation, and Exchange of Identification Records; Appointment of Officials, June 11, 1930; Public Law 109-177 (H.R. 3199), March 9, 2006, USA Patriot Improvement and Reauthorization Act of 2005; Public Law 110-457, Title II, Section 237(a), (b), December 23, 2008, the William Wilberforce Trafficking Victims Reauthorization Act of 2008, and Matthew Shepard Hate Crimes Prevention Act, April 28, 2009, this collection requests incident data from city, county, state, tribal and federal law enforcement agencies in order for the FBI UCR Program to serve as the national clearinghouse for the collection and dissemination of crime data and to publish these statistics in Crime in the United States, Hate Crime Statistics, and Law Enforcement Officers Killed and Assaulted. NIBRS is an incident-based reporting system in which law enforcement collects data on each crime occurrence. Designed to be generated as a byproduct of local, state, and federal automated records systems, currently, the NIBRS collects data on each incident and arrest within 23 crime categories made up of 49 specific crimes called Group A offenses. For each of the offenses coming to the attention of law enforcement, various facts about the crime are collected. In addition to the Group A offenses, there are 10 Group B offense categories for which only arrest data are reported. The most significant difference between NIBRS and the traditional Summary Reporting System (SRS) is the degree of detail in reporting. In reporting data via the traditional SRS, law enforcement agencies tally the occurrences of eight Part I crimes. NIBRS is capable of producing more detailed, accurate, and meaningful data because data are collected about when and where crime takes place, what form

it takes, and the characteristics of its victims and perpetrators. Although most of the general concepts for collecting, scoring, and reporting UCR data in the SRS apply in the NIBRS, such as jurisdictional rules, there are some important differences in the two systems. The most notable differences that give the NIBRS an advantage over the SRS are: No Hierarchy Rule, in a multiple-offense incident NIBRS reports every offense occurring during the incident where SRS would report just the most serious offense and the lower-listed offense would not be reported; NIBRS provides revised, expanded, and new offense definitions; NIBRS provides more specificity in reporting offenses, using NIBRS offense and arrest data for 23 Group A offense categories can be reported while in the SRS eight Part I offenses can be reported; NIBRS can distinguish between attempted and completed Group A crimes; NIBRS also provides crimes against society while the SRS does not; the victim-to-offender data, circumstance reporting, drug related offenses, offenders suspected use of drugs, and computer crime is expanded in NIBRS; the NIBRS update reports are directly tied to the original incident submitted. The Group A offense categories include arson, assault offenses, bribery, burglary/breaking and entering, counterfeiting/forgery, destruction/damage/vandalism of property, drug/narcotic offenses, embezzlement, extortion/blackmail, fraud offenses, gambling offenses, homicide offenses, human trafficking, kidnapping/abduction, larceny/theft offenses, motor vehicle theft, pornography/obscene material, prostitution offenses, robbery, sex offenses, sex offenses/nonforcible, stolen property offenses, and weapon law violations. The Group B offense categories include bad checks, curfew/loitering/vagrancy violations, disorderly conduct, DUI, drunkenness, family offenses/nonviolent, liquor law violations, peeping tom, trespass of real property, and all other offenses.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are approximately 6,420 law enforcement agencies. The amount of time estimated for an average respondent to respond is two hours monthly which totals to an annual hour burden of 24 hours. The 2 hours to respond is the time it takes for the agencies records management system (RMS) to download the NIBRS and send to the FBI. By design, law enforcement agencies generate NIBRS data as a by-product of their RMS. Therefore, a law

enforcement agency builds its system to suit its own individual needs, including all of the information required for administration and operation; then forwards only the data required by the NIBRS to participate in the FBI UCR Program.

(6) *An estimate of the total public burden (in hours) associated with this collection:* There are approximately 154,080 hours, annual burden, associated with this information collection. The total number of respondents is 6,420 with a total annual hour burden of 24 hours, (6,420 × 24 = 154,080 total annual hours).

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE., Room 3E.405B, Washington, DC 20530.

Dated: October 13, 2015.

Jerri Murray,

Department Clearance Officer PRA, United States Department of Justice.

[FR Doc. 2015-26357 Filed 10-15-15; 8:45 am]

BILLING CODE 4410-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1110-0048]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension of a Currently Approved Collection Cargo Theft Incident Report

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division will be submitting the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the established review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** at 80 FR 48574, on August 13, 2015, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions

regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Mr. Samuel Berhanu, Unit Chief, Federal Bureau of Investigation, CJIS Division, Module E-3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; facsimile (304) 625-3566. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *The Title of the Form/Collection:* Cargo Theft Incident Report.

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection:* Form Number: 1110-0048. Sponsor: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: City, county, state, federal, and tribal law enforcement agencies. Abstract: This collection is needed to collect information on cargo theft incidents committed throughout the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are approximately 18,415 law enforcement agency respondents that submit monthly for a total of 220,980 responses with an estimated response time of 5 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with this collection:* There are approximately 18,415 hours, annual burden, associated with this information collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE., Room 3E.405B, Washington, DC 20530.

Dated: October 13, 2015.

Jerri Murray,

Department Clearance Officer for PRA, United States Department of Justice.

[FR Doc. 2015-26356 Filed 10-15-15; 8:45 am]

BILLING CODE 4410-02-P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for the Self-Employment Training (SET) Demonstration Evaluation (SET Evaluation); Extension Request Without Change to an Existing Collection

AGENCY: Employment and Training Administration (ETA); Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the 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 (PRA) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that required 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 Department notes that a Federal agency cannot conduct or sponsor a collection of information unless it is approved by the Office of Management

and Budget (OMB) under the PRA and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (see 5 CFR 1320.5(a) and 1320.6).

This information collection request (ICR) is to obtain extended clearance for Mathematica Policy Research, under contract to ETA, to administer the follow-up survey for the SET Evaluation. A 20-month extension is requested to the data-collection period for the follow-up survey.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before December 15, 2015.

ADDRESSES: Send comments to Janet Javar, U.S. Department of Labor, Room S-2312, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: (202) 693-5954 (this is not a toll-free number). Email address: javar.janet.o@dol.gov. Fax number: (202) 693-5961 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background: ETA seeks to implement and rigorously evaluate the effectiveness of innovative strategies for promoting employment based on the authority granted to the agency under the Workforce Innovation and Opportunity Act and, formerly, the Workforce Investment Act. The SET Demonstration focuses specifically on self-employment as a reemployment strategy for dislocated workers. The demonstration is premised on the hypotheses that: (1) Self-employment could be a viable strategy for dislocated workers to become reemployed; (2) starting a small business is difficult, especially for individuals who lack business expertise or access to start-up capital; and (3) dislocated workers might experience difficulties locating and accessing training and counseling services that could effectively prepare them for self-employment via the existing workforce infrastructure.

The SET Demonstration will implement a new service delivery model that seeks to better connect dislocated workers to self-employment services. This approach differs from previous large-scale demonstration programs, which have provided mixed evidence on the effectiveness of self-employment services on earnings and

employment, because the SET Demonstration will: (1) Rely on self-employment advisors to offer more intensive business development counseling services than prior demonstrations have offered; and (2) concentrate on dislocated workers who have fairly limited traditional employment prospects but are well-positioned to benefit from self-employment counseling and training. The SET Evaluation will assess the effectiveness of the SET Demonstration model.

To achieve the study's target sample size, enrollment in the SET program began in July 2013 and will continue through December 2015. About 3,000 eligible applicants will be randomly assigned to either receive SET services or to a control group. All 3,000 applicants are asked to complete the 18-month follow-up survey.

An initial clearance request for the SET Evaluation was approved by OMB in January 2013 (ICR reference number 201209-1205-001; OMB control number 1205-0505). Clearance covered the study's consent and application forms, the program participation records, the evaluation team's site visit and case study protocols, and the study participant follow-up survey. This data collection was approved with an expiration date of January 31, 2016 and an annualized total allowable burden of 5,344 hours.

A subsequent non-substantive change request related to the follow-up survey (ICR reference number 201408-1205-005) was approved by OMB in October 2014. This non-substantive request sought to preserve the most critical outcome measures while shortening instrument length to reduce respondent burden. The non-substantive change did not affect any data collection efforts other than the follow-up survey. As with the originally approved OMB package, all 3,000 applicants would be asked to complete the survey, but the shortening of the instrument will reduce the total annualized burden across the entire study from 5,344 to 4,277 hours.

This new request is to extend OMB clearance of the follow-up survey administration, which will expire on January 31, 2016, for an additional 20 months, to September 30, 2017. Given that study enrollment has proceeded more slowly than originally planned, an 18-month follow-up survey could be administered to only approximately 25 percent of the demonstration applicants by the current expiration date of January 31, 2016. Assuming an 80 percent response rate, this would result in approximately 630 respondents (= 3,000 respondents × 0.80 response rate × 0.25

of study participants). Extending the expiration date to September 30, 2017 will allow sufficient time to field the survey to all study applicants. This request does not cover any of the other elements of the OMB-approved data collection; no extension is required for the consent and application forms, the program participation records, or the evaluation team's site visit and case study protocols.

The 18-month follow-up survey is administered 18 months after study participants apply to the SET program. It is the only source of information needed to evaluate the impact program on the six groups of study outcomes: (1) Current employment status; (2) receipt of self-employment assistance services; (3) business development activities; (4) self-employment experiences; (5) experiences in wage and salary employment; and (6) job satisfaction and program participation. These data will be used to determine the impacts of the SET Demonstration on participants' outcomes.

Desired Focus of Comments:

Currently, the Department of Labor is soliciting comments concerning the above data collection. Comments are requested to:

- * Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- * evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- * enhance the quality, utility, and clarity of the information to be collected; and

- * minimize the burden of the information collection on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Current Actions: At this time, the Department is requesting clearance for a 20-month extension of time allowed to complete the SET Evaluation's 18-month follow-up survey.

Type of review: Extension without a change.

Title of Collection: Self-Employment Training Demonstration Evaluation.

OMB Control Number: 1205-0505.

Affected Public: Dislocated workers who applied for services available through the SET Demonstration.

Cite/Reference/Form/etc.: Workforce Investment Act of 1998, Section 172

(Pub. L. 105–220) and Workforce

Innovation and Opportunity Act,
Section 169 (Pub. L. 113–128).

ANNUAL BURDEN ESTIMATES FOR THE SET DEMONSTRATION EVALUATION 18-MONTH FOLLOW-UP SURVEY BETWEEN
FEBRUARY 1, 2016 AND SEPTEMBER 30, 2017

Activity	Number of respondents ¹	Responses per respondent	Average time per response	Total respondent burden (hours)
18-Month Follow-Up Survey	1,770	1	20 minutes	590

¹ Attempts will be made to complete interviews with all 3,000 eligible applicants who went through random assignment. Given the targeted response rate of 80 percent, interviews are expected to be completed with 2,400 sample members. The 18-Month follow-up survey will be fielded through September 30, 2017. Interviews with 630 sample members are expected to be completed by January 31, 2016, when the current OMB clearance expires. Another 1,770 interviews are expected to be completed between February 1, 2016 and September 30, 2017, the extension proposed in this request.

This request includes no changes to the follow-up survey instrument, and therefore implies no change in total respondent burden. The study team expects to complete 2,400 interviews, as originally planned, for a response rate of 80 percent. A total of 210 burden hours ((= 630 responses × 20 minutes per response) ÷ 60 minutes/hour) are anticipated for surveys completed prior to the expiration date. As seen in the table above, another 590 burden hours ((= 1,770 responses × 20 minutes/response) ÷ 60 minutes/hour) would occur for surveys completed during the extension period, if granted. The total burden for the follow-up survey as a whole would remain unchanged at 800 hours, the amount originally approved by OMB.

The extension would also reduce the average annualized burden hours because the survey fielding would occur over a longer period than originally planned. The original OMB clearance package assumed that the fielding period would last for 18 months, which implied an average annualized hour burden of 533 (= 800 total hours/1.5 years). Given study enrollment patterns, the follow-up survey began in early April 2015, and the fielding period will last until September 2017 if the extension is granted, for a total of 30 months. The longer fielding period implied a reduction in the average annualized hour burden of 320 (= 800 total hours/2.5 years). If granted, the extension would result in an average annualized dollar burden of \$5,737 ((= 2,400 responses × 20 minutes/response) ÷ (60 minutes/hour × \$17.93 per hour/2.5 years)), which is lower than under the plan originally approved by OMB.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval; they will also become a matter of public record.

Signed:
Portia Wu,
Assistant Secretary for Employment and Training, Labor.
[FR Doc. 2015–26373 Filed 10–15–15; 8:45 am]
BILLING CODE 4510–FT–P

Dated: October 8, 2015.
Lisette Voyatzis,
Committee Management Officer.
[FR Doc. 2015–26381 Filed 10–15–15; 8:45 am]
BILLING CODE 7536–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meetings of Humanities Panel; Correction

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of Meetings; correction.

SUMMARY: The National Endowment for the Humanities published a document in the **Federal Register** of September 16, 2015, concerning notice of meetings of the Humanities Panel during the month of October, 2015. One meeting date has changed. All other information in the notice remains the same.

FOR FURTHER INFORMATION CONTACT: Lisette Voyatzis, Committee Management Officer; (202) 606–8322; *evoyatzis@neh.gov*.

Correction

In the **Federal Register** of September 16, 2015, in FR Doc. 2015–23205, on page 55650, in the first column, replace item 16 with:

- 16. DATE: October 30, 2015.
- TIME: 8:30 a.m. to 5:00 p.m.
- ROOM: Virtual Meeting.

This meeting will discuss applications on the subject of Linguistics, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of meetings.

SUMMARY: The National Endowment for the Humanities will hold twenty-six meetings of the Humanities Panel, a federal advisory committee, during November, 2015. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965.

DATES: See Supplementary Information section for meeting dates.

ADDRESSES: The meetings will be held at Constitution Center at 400 7th Street SW., Washington, DC 20506. See **SUPPLEMENTARY INFORMATION** for meeting room numbers.

FOR FURTHER INFORMATION CONTACT: Lisette Voyatzis, Committee Management Officer, 400 7th Street SW., Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov*. Hearing-impaired individuals who prefer to contact us by phone may use NEH’s TDD terminal at (202) 606–8282.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

- 1. DATE: November 2, 2015

TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 4002
This meeting will discuss applications on the subjects of U.S. History and Culture, for Museums, Libraries, and Cultural Organizations: Implementation Grants, submitted to the Division of Public Programs.

2. DATE: November 2, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs.

3. DATE: November 3, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P002
This meeting will discuss applications on the subjects of Music and Performing Arts, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

4. DATE: November 3, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs.

5. DATE: November 3, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications on the subject of History, for Media Projects: Development Grants, submitted to the Division of Public Programs.

6. DATE: November 4, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 4002
This meeting will discuss applications on the subjects of U.S. History and Culture, for Museums, Libraries, and Cultural Organizations: Implementation Grants, submitted to the Division of Public Programs.

7. DATE: November 4, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs.

8. DATE: November 5, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P002
This meeting will discuss applications on the subjects of Art and Architectural History, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

9. DATE: November 5, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call

This meeting will discuss applications on the subjects of U.S. History and Culture, for Museums, Libraries, and Cultural Organizations: Planning Grants, submitted to the Division of Public Programs.

10. DATE: November 5, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs.

11. DATE: November 9, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications on the subjects of Arts and Culture, for Media Projects: Development Grants, submitted to the Division of Public Programs.

12. DATE: November 9, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications for Enduring Questions: Pilot Course Grants, submitted to the Division of Education Programs.

13. DATE: November 10, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P002
This meeting will discuss applications on the subjects of Contemporary U.S. History and Culture, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

14. DATE: November 10, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications on the subject of American Studies, for Museums, Libraries, and Cultural Organizations: Planning Grants, submitted to the Division of Public Programs.

15. DATE: November 12, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Conference Call
This meeting will discuss applications on the subjects of Art and Design, for Museums, Libraries, and Cultural Organizations: Planning Grants, submitted to the Division of Public Programs.

16. DATE: November 13, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P002
This meeting will discuss applications on the subject of World Studies: Early Modern Era to Present, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

17. DATE: November 16, 2015

TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 4002
This meeting will discuss applications on the subjects of Archives and Digital Collections I (Level II), for Digital Humanities Start-Up Grants, submitted to the Office of Digital Humanities.

18. DATE: November 16, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P003
This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

19. DATE: November 17, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P002
This meeting will discuss applications on the subject of World Studies: Classic Era to Medieval, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

20. DATE: November 17, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P003
This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

21. DATE: November 17, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 4002
This meeting will discuss applications on the subject of Geospatial and Visualization (Level II), for Digital Humanities Start-Up Grants, submitted to the Office of Digital Humanities.

22. DATE: November 18, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 4084
This meeting will discuss applications on the subjects of Media Studies and Scholarly Communication (Level II), for Digital Humanities Start-Up Grants, submitted to the Office of Digital Humanities.

23. DATE: November 18, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: 4075
This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

24. DATE: November 23, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: Virtual Panel
This meeting will discuss applications on the subjects of Public Programs and Education (Level I), for Digital Humanities Start-Up Grants, submitted to the Office of Digital Humanities.

25. DATE: November 23, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P003

This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

26. DATE: November 24, 2015
TIME: 8:30 a.m. to 5:00 p.m.
ROOM: P003

This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. 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: October 8, 2015.

Lisette Voyatzis,
Committee Management Officer.

[FR Doc. 2015-26380 Filed 10-15-15; 8:45 am]

BILLING CODE 7536-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2015-0001]

Sunshine Act Meeting Notice

DATE: October 19, 26, November 2, 9, 16, 23, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of October 19, 2015

Monday, October 19, 2015

9:30 a.m. Briefing on Security Issues
(Closed—Ex. 1)

Wednesday, October 21, 2015

9 a.m. Joint Meeting of the Federal Energy Regulatory Commission (FERC) and the Nuclear Regulatory Commission (NRC) (Part 1) (Public Meeting) To be held at FERC Headquarters, 888 First Street NE., Washington, DC. (Contact: Tania Martinez-Navedo: 301-415-6561)
This meeting will be webcast live at the Web address—www.ferc.gov.

11:20 a.m. Joint Meeting of the Federal Energy Regulatory Commission

(FERC) and the Nuclear Regulatory Commission (NRC) (Part 2) (Closed—Ex. 1 & 3) To be held at FERC Headquarters, 888 First Street NE., Washington, DC.

Week of October 26, 2015—Tentative

There are no meetings scheduled for the week of October 26, 2015.

Week of November 2, 2015—Tentative

There are no meetings scheduled for the week of November 2, 2015.

Week of November 9, 2015—Tentative

There are no meetings scheduled for the week of November 9, 2015.

Week of November 16, 2015—Tentative

Tuesday, November 17, 2015

9 a.m. Briefing on the Status of Lessons Learned from the Fukushima Dai-ichi Accident (Public Meeting)
(Contact: Gregory Bowman: 301-415-2939)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

Thursday, November 19, 2015

9 a.m. Hearing on Combined Licenses for South Texas Project, Units 3 and 4: Section 189a. of the Atomic Energy Act Proceeding (Public Meeting)

(Contact: Tom Tai: 301-415-8484)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

Week of November 23, 2015—Tentative

There are no meetings scheduled for the week of November 23, 2015.

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at Denise.McGovern@nrc.gov.

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The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/public-involve/public-meetings/schedule.html>.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301-287-0727, by videophone at 240-428-3217, or by email at Kimberly.Meyer-Chambers@nrc.gov. Determinations on requests for

reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or email Brenda.Akstulewicz@nrc.gov or Patricia.Jimenez@nrc.gov.

Dated: October 14, 2015.

Denise McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2015-26482 Filed 10-14-15; 4:15 pm]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76117; File No. TP 15-19]

Order Granting Limited Exemptions From Exchange Act Rule 10b-17 and Rules 101 and 102 of Regulation M to PowerShares DWA Tactical Sector Rotation Portfolio Pursuant to Exchange Act Rule 10b-17(b)(2) and Rules 101(d) and 102(e) of Regulation M

October 8, 2015.

By letter dated October 8, 2015 (the "Letter"), as supplemented by conversations with the staff of the Division of Trading and Markets, counsel for PowerShares Exchange-Traded Fund Trust II (the "Trust"), on behalf of the Trust, PowerShares DWA Tactical Sector Rotation Portfolio (the "Fund"), any national securities exchange on or through which shares issued by the Fund ("Shares") may subsequently trade, Invesco Distributors, Inc. (the "Distributor"), and persons or entities engaging in transactions in Shares (collectively, the "Requestors"), requested exemptions, or interpretive or no-action relief, from Rule 10b-17 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and Rules 101 and 102 of Regulation M, in connection with secondary market transactions in Shares and the creation or redemption of aggregations of Shares of at least 50,000 shares ("Creation Units").

The Trust is registered with the Securities and Exchange Commission ("Commission") under the Investment Company Act of 1940, as amended ("1940 Act"), as an open-end management investment company. The Fund seeks to track the performance of the underlying index, the Dorsey Wright® Sector 4 Index (the "Index").

The Fund intends to operate as an “ETF of ETFs” by seeking to track the performance of its underlying Index through, under normal circumstances, investing at least 90% of its total assets in the ETFs that comprise the Index, and may include U.S. Treasury Bills.¹ Except for the fact that the Fund will operate as an ETF of ETFs, the Fund will operate in a manner identical to the ETFs that are included in the Index.

The Requestors represent, among other things, the following:

- Shares of the Fund will be issued by the Trust, an open-end management investment company that is registered with the Commission;
- The Trust will continuously redeem Creation Units at net asset value (“NAV”), and the secondary market price of the Shares should not vary substantially from the NAV of such Shares;
- Shares of the Fund will be listed and traded on the NASDAQ Stock Market LLC or another exchange in accordance with exchange listing standards that are, or will become, effective pursuant to Section 19(b) of the Exchange Act (the “Exchange”);²
- All ETFs in which the Fund is invested will meet all conditions set forth in a relevant class relief letter,³ will have received individual relief from the Commission, or will be able to rely upon individual relief even though they

¹ At any point, the Index comprises up to four PowerShares ETFs from a set of nine eligible PowerShares ETFs. During market periods when fewer than four eligible PowerShares ETFs demonstrate sufficient relative strength, however, the Index may hold up to a 100% cash position, represented by U.S. Treasury Bills with a duration ranging from 0–180 days, in an amount equal to the weight of the PowerShares ETFs that would otherwise be included in the Index.

² Further, the Letter states that should the Shares also trade on a market pursuant to unlisted trading privileges, such trading will be conducted pursuant to self-regulatory organization rules that have become effective pursuant to Section 19(b) of the Exchange Act.

³ Exchange Act Rel. No. 67215 (June 19, 2012); 77 FR 37941 (June 25, 2012); Letter from Catherine McGuire, Esq., Chief Counsel, Division of Market Regulation, to the Securities Industry Association Derivative Products Committee (November 21, 2005); Letter from Raquel L. Russell, Branch Chief, Division of Market Regulation, to George T. Simon, Esq., Foley & Lardner LLP (June 21, 2006); Letter from James A. Brigagliano, Acting Associate Director, Division of Market Regulation, to Stuart M. Strauss, Esq., Clifford Chance US LLP (October 24, 2006); Letter from James A. Brigagliano, Associate Director, Division of Market Regulation, to Benjamin Haskin, Esq., Willkie Farr & Gallagher LLP (April 9, 2007); Letter from Josephine Tao, Assistant Director, Division of Trading and Markets, to Domenick Pugliese, Esq., Paul, Hastings, Janofsky & Walker LLP (June 27, 2007); see also Staff Legal Bulletin No. 9, “Frequently Asked Questions About Regulation M” (April 12, 2002) (regarding actively-managed ETFs).

are not named parties (for example, a no-action letter);

- At least 70% of the Fund is comprised of component securities that will meet the minimum public float and minimum average daily trading volume thresholds under the “actively-traded securities” definition found in Regulation M for excepted securities during each of the previous two months of trading prior to formation of the Fund;

- All the components of the Index will have publicly available last sale trade information;
- The intra-day proxy value of the Fund per share and the value of the Index will be publicly disseminated by a major market data vendor throughout the trading day;
- On each business day before the opening of business on the Exchange, the Fund’s custodian, through the National Securities Clearing Corporation, will make available the list of the names and the numbers of securities and other assets of the Fund’s portfolio that will be applicable that day to creation and redemption requests;
- The Exchange or other market information provider will disseminate (i) continuously every 15 seconds throughout the trading day, through the facilities of the consolidated tape, the market value of a Share, and (ii) every 15 seconds throughout the trading day, a calculation of the intra-day indicative value of a Share;

- The arbitrage mechanism will be facilitated by the transparency of the Fund’s portfolio and the availability of the intra-day indicative value, the liquidity of securities held by the Fund, and the ability to acquire such securities, as well as the arbitrageurs’ ability to create workable hedges;

- The Fund will invest solely in liquid securities;
- The Fund will invest in securities that will facilitate an effective and efficient arbitrage mechanism and the ability to create workable hedges;
- The Trust believes that arbitrageurs are expected to take advantage of price variations between the Fund’s market price and its NAV; and
- A close alignment between the market price of Shares and the Fund’s NAV is expected.

Regulation M

While redeemable securities issued by an open-end management investment company are excepted from the provisions of Rules 101 and 102 of Regulation M, the Requestors may not rely upon those exceptions for the

Shares.⁴ However, we find that it is appropriate in the public interest and is consistent with the protection of investors to grant a conditional exemption from Rules 101 and 102 to persons who may be deemed to be participating in a distribution of Shares of the Fund as described in more detail below.

Rule 101 of Regulation M

Generally, Rule 101 of Regulation M is an anti-manipulation rule that, subject to certain exceptions, prohibits any “distribution participant” and its “affiliated purchasers” from bidding for, purchasing, or attempting to induce any person to bid for or purchase any security that is the subject of a distribution until after the applicable restricted period, except as specifically permitted in the Rule. Rule 100 of Regulation M defines “distribution” to mean any offering of securities that is distinguished from ordinary trading transactions by the magnitude of the offering and the presence of special selling efforts and selling methods. The provisions of Rule 101 of Regulation M apply to underwriters, prospective underwriters, brokers, dealers, or other persons who have agreed to participate or are participating in a distribution of securities. The Shares are in a continuous distribution, and, as such, the restricted period in which distribution participants and their affiliated purchasers are prohibited from bidding for, purchasing, or attempting to induce others to bid for or purchase extends indefinitely.

Based on the representations and the facts presented in the Letter, particularly that the Trust is a registered open-end management investment company that will continuously redeem at the NAV Creation Unit size aggregations of the Shares of the Fund and that a close alignment between the market price of Shares and the Fund’s NAV is expected, the Commission finds that it is appropriate in the public interest, and consistent with the protection of investors to grant the Trust an exemption under paragraph (d) of Rule 101 of Regulation M with respect to the Fund, thus permitting persons participating in a distribution of Shares of the Fund to bid for or purchase such Shares during their participation in such distribution.⁵

⁴ While ETFs operate under exemptions from the definitions of “open-end company” under Section 5(a)(1) of the 1940 Act and “redeemable security” under Section 2(a)(32) of the 1940 Act, the Fund and its securities do not meet those definitions.

⁵ Additionally, we confirm the interpretation that a redemption of Creation Unit size aggregations of

Rule 102 of Regulation M

Rule 102 of Regulation M prohibits issuers, selling security holders, and any affiliated purchaser of such person from bidding for, purchasing, or attempting to induce any person to bid for or purchase a covered security during the applicable restricted period in connection with a distribution of securities effected by or on behalf of an issuer or selling security holder.

Based on the representations and the facts presented in the Letter, particularly that the Trust is a registered open-end management investment company that will redeem at the NAV Creation Unit size aggregations of Shares of the Fund and that a close alignment between the market price of Shares and the Fund's NAV is expected, the Commission finds that it is appropriate in the public interest, and consistent with the protection of investors to grant the Trust an exemption under paragraph (e) of Rule 102 of Regulation M with respect to the Fund, thus permitting the Fund to redeem Shares of the Fund during the continuous offering of such Shares.

Rule 10b-17

Rule 10b-17, with certain exceptions, requires an issuer of a class of publicly traded securities to give notice of certain specified actions (for example, a dividend distribution) relating to such class of securities in accordance with Rule 10b-17(b). Based on the representations and the facts presented in the Letter, and subject to the conditions below, the Commission finds that it is appropriate in the public interest, and consistent with the protection of investors, to grant the Trust a conditional exemption from Rule 10b-17 because market participants will receive timely notification of the existence and timing of a pending distribution, and thus the concerns that the Commission raised in adopting Rule 10b-17 will not be implicated.⁶

Conclusion

It is hereby ordered, pursuant to Rule 101(d) of Regulation M, that the Trust, based on the representations and facts

Shares of the Fund and the receipt of securities in exchange by a participant in a distribution of Shares of the Fund would not constitute an "attempt to induce any person to bid for or purchase[] a covered security during the applicable restricted period" within the meaning of Rule 101 of Regulation M and therefore would not violate that rule.

⁶ We also note that timely compliance with Rule 10b-17(b)(1)(v)(a) and (b) would be impractical in light of the Fund's nature because it is not possible for the Fund to accurately project ten days in advance what dividend, if any, would be paid on a particular record date.

presented in the Letter, is exempt from the requirements of Rule 101 with respect to the Fund, thus permitting persons who may be deemed to be participating in a distribution of Shares of the Fund to bid for or purchase such Shares during their participation in such distribution.

It is further ordered, pursuant to Rule 102(e) of Regulation M, that the Trust, based on the representations and the facts presented in the Letter, is exempt from the requirements of Rule 102 with respect to the Fund, thus permitting the Fund to redeem Shares of the Fund during the continuous offering of such Shares.

It is further ordered, pursuant to Rule 10b-17(b)(2), that the Trust, based on the representations and the facts presented in the Letter and subject to the conditions below, is exempt from the requirements of Rule 10b-17 with respect to the transactions in the Shares of the Fund.

This exemptive relief is subject to the following conditions:

- The Trust will comply with Rule 10b-17, except for Rule 10b-17(b)(1)(v)(a) and (b); and
- The Trust will provide the information required by Rule 10b-17(b)(1)(v)(a) and (b) to the Exchange as soon as practicable before trading begins on the ex-dividend date, but in no event later than the time when the Exchange last accepts information relating to distributions on the day before the ex-dividend date.

This exemptive relief is subject to modification or revocation at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Exchange Act. This exemption is based on the facts presented and the representations made in the Letter. Any different facts or representations may require a different response. Persons relying upon this exemptive relief shall discontinue transactions involving the Shares of the Fund, pending presentation of the facts for the Commission's consideration, in the event that any material change occurs with respect to any of the facts or representations made by the Requestors, and as is the case with all preceding letters, particularly with respect to the close alignment between the market price of Shares and the Fund's NAV. In addition, persons relying on this exemption are directed to the anti-fraud and anti-manipulation provisions of the Exchange Act, particularly Sections 9(a), 10(b), and Rule 10b-5 thereunder. Responsibility for compliance with these and any other applicable provisions of the federal securities laws

must rest with the persons relying on this exemption. This Order should not be considered a view with respect to any other question that the proposed transactions may raise, including, but not limited to, the adequacy of the disclosure concerning, and the applicability of other federal or state laws to, the proposed transactions.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-26329 Filed 10-15-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76121; File No. SR-FINRA-2015-037]

**Self-Regulatory Organizations;
Financial Industry Regulatory
Authority, Inc.; Notice of Filing and
Immediate Effectiveness of a Proposed
Rule Change To Extend the TRACE
Pilot Program in FINRA Rule 6730(e)(4)**

October 9, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 28, 2015, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a "non-controversial" rule change under paragraph (f)(6) of Rule 19b-4 under the Act,³ which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's
Statement of the Terms of Substance of
the Proposed Rule Change**

FINRA is proposing to extend the pilot program in FINRA Rule 6730(e)(4) to October 27, 2017. The pilot program exempts from TRACE reporting transactions in TRACE-Eligible Securities that are executed on a facility of the New York Stock Exchange

⁷ 17 CFR 200.30-3(a)(6) and (9).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 17 CFR 240.19b-4(f)(6).

(“NYSE”), subject to specified conditions.

Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

6700. TRADE REPORTING AND COMPLIANCE ENGINE (TRACE)

* * * * *

6730. Transaction Reporting

(a) through (d) No Change.

(e) Reporting Requirements for Certain Transactions and Transfers of Securities

The following shall not be reported:

(1) through (3) No Change.

(4) Provided that a data sharing agreement between FINRA and NYSE related to transactions covered by this Rule remains in effect, for a pilot program expiring on [October 23, 2015] *October 27, 2017*, transactions in TRACE-Eligible Securities that are executed on a facility of NYSE in accordance with NYSE Rules 1400, 1401 and 86 and reported to NYSE in accordance with NYSE’s applicable trade reporting rules and disseminated publicly by NYSE.

(5) through (6) No Change.

(f) No Change.

* * * Supplementary Material:

.01 through .02 No Change.

* * * * *

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA Rule 6730(e)(4) exempts members from reporting to the Trade Reporting and Compliance Engine (“TRACE”) transactions in TRACE-Eligible Securities⁴ that are executed on

a facility of NYSE in accordance with specified NYSE rules and that are reported to NYSE and disseminated publicly, provided that a data sharing agreement between FINRA and NYSE related to transactions covered by FINRA Rule 6730 remains in effect. This exemption operates as a pilot program and is currently scheduled to expire on October 23, 2015.⁵

FINRA is proposing to extend the pilot program for two years until October 27, 2017. Thus, members would continue to be exempted from reporting to TRACE transactions in TRACE-Eligible Securities that are executed on an NYSE facility in accordance with NYSE Rules 1400, 1401 and 86, where such transactions are reported to NYSE in accordance with NYSE’s applicable trade reporting rules, and disseminated publicly by NYSE.⁶

FINRA is proposing to extend the pilot to provide additional time to analyze the impact of the exemption and to avoid duplicative reporting

private issuer, and, if a “restricted security” as defined in Securities Act Rule 144(a)(3), sold pursuant to Securities Act Rule 144A; or is a debt security that is U.S. dollar-denominated and issued or guaranteed by an Agency as defined in paragraph (k) or a Government-Sponsored Enterprise as defined in paragraph (n). “TRACE-Eligible Security” does not include a debt security that is: Issued by a foreign sovereign, a U.S. Treasury Security as defined in paragraph (p), or a Money Market Instrument as defined in paragraph (o).

⁵ See Securities Exchange Act Release No. 54768 (November 16, 2006), 71 FR 67673 (November 22, 2006) (Order Approving File No. SR-NASD-2006-110) (pilot program in FINRA Rule 6730(e)(4), subject to the execution of a data sharing agreement addressing relevant transactions, became effective on January 9, 2007); Securities Exchange Act Release No. 59216 (January 8, 2009), 74 FR 2147 (January 14, 2009) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2008-065) (pilot program extended to January 7, 2011); Securities Exchange Act Release No. 63673 (January 7, 2011), 76 FR 2739 (January 14, 2011) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2011-002) (pilot program extended to July 8, 2011); Securities Exchange Act Release No. 64665 (June 14, 2011), 76 FR 35933 (June 20, 2011) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2011-025) (pilot program extended to January 27, 2012); Securities Exchange Act Release No. 66018 (December 21, 2011), 76 FR 81549 (December 28, 2011) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2011-072) (pilot program extended to October 26, 2012); Securities Exchange Act Release No. 68076 (October 22, 2012), 77 FR 65431 (October 26, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2012-047) (pilot program extended to October 25, 2013); and Securities Exchange Act Release No. 70288 (August 29, 2013), 78 FR 54694 (September 5, 2013) (Notice of Filing and Immediate Effectiveness of File No. SR-FINRA-2013-038) (pilot program extended to October 23, 2015).

⁶ The success of the pilot program remains dependent on FINRA’s ability to continue to effectively conduct surveillance for TRACE-Eligible Securities. The exemption, therefore, continues to be conditional on a data sharing agreement being in effect between FINRA and NYSE related to transactions covered by FINRA Rule 6730.

requirements for members with regard to transactions in these securities, which otherwise would be subject to trade reporting to both FINRA and NYSE. However, FINRA supports a regulatory construct that, in the future, consolidates all last sale transaction information to provide better price transparency and a more efficient means to engage in market surveillance of TRACE-Eligible Securities transactions. The proposed extension would allow the pilot program to continue to operate without interruption while FINRA and NYSE continue to assess the effect of the exemption and issues regarding the consolidation of market data, market surveillance and price transparency.

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date will be October 23, 2015.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,⁷ which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

FINRA believes that extension of the pilot protects investors and the public because it continues to ensure that transactions are required to be reported and publicly disseminated; therefore, transparency will be maintained for these transactions. The continued condition that a data sharing agreement remain in effect between NYSE and FINRA for transactions covered by the FINRA Rule 6730(e)(4) exemption allows FINRA to continue to conduct surveillance in TRACE-Eligible Securities. In addition, extending the exemption permits members that are subject to both FINRA’s and NYSE’s trade reporting requirements to avoid a duplicative regulatory structure and the increased costs that may be incurred as a result of such duplicative requirements.

B. Self-Regulatory Organization’s Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the extension of the exemptive provision does not result in any burden on competition since it allows members that are subject to both

⁴ Rule 6710(a) provides that a “TRACE-Eligible Security” is a debt security that is United States dollar-denominated and issued by a U.S. or foreign

⁷ 15 U.S.C. 78o-3(b)(6).

FINRA's and NYSE's trade reporting requirements to avoid a duplicative regulatory structure and the increased costs that may be incurred as a result of such duplicative requirements.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act⁸ and Rule 19b-4(f)(6)⁹ thereunder.

FINRA has asked the Commission to waive the 30-day operative delay so that the pilot may continue to operate without interruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. This action will continue to allow the benefits of the pilot—preventing duplicative reporting of transactions in TRACE-Eligible Securities that occur on NYSE—to continue without interruption. Therefore, the Commission hereby designates the proposed rule change as operative upon filing.¹⁰

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

⁸ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), FINRA provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

¹⁰ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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-FINRA-2015-037 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-FINRA-2015-037. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-FINRA-2015-037 and should be submitted on or before November 6, 2015.

¹¹ 17 CFR 200.30-3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Robert W. Errett,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76126; File No. SR-NASDAQ-2015-095]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Granting Approval of Proposed Rule Change Relating to the Listing and Trading of the Shares of the AltShares Long/Short High Yield Fund of ETFs Series Trust I

October 9, 2015.

I. Introduction

On August 7, 2015, The NASDAQ Stock Market LLC (the "Exchange" or "Nasdaq") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to list and trade shares ("Shares") of the AltShares Long/Short High Yield Fund ("Fund") of ETFs Series Trust I ("Trust") under NASDAQ Rule 5735. The proposed rule change was published for comment in the **Federal Register** on August 25, 2015.³ The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change.

II. Description of the Proposal

The Exchange proposes to list and trade the Shares under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange. The Fund will be an actively-managed exchange-traded fund ("ETF"). The Shares will be offered by the Trust,⁴ which is registered with the Commission as an investment company and has filed a registration statement on Form N-1A ("Registration Statement")

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 75738 (August 19, 2015), 80 FR 51632 ("Notice").

⁴ According to the Exchange, the Adviser (as defined herein) has obtained certain exemptive relief, upon which the Trust may rely, under the Investment Company Act of 1940 ("1940 Act"). See Investment Company Act Release No. 30607 (July 23, 2013) (File No. 812-14080).

with the Commission.⁵ The Fund will be a series of the Trust.

Etfis Capital LLC will be the investment adviser (“Adviser”) to the Fund, and Bramshill Investments, LLC will be the investment sub-adviser to the Fund (“Sub-Adviser”). ETF Distributors LLC (“Distributor”) will be the principal underwriter and distributor of the Fund’s Shares. The Bank of New York Mellon Corporation (“BNY”) will act as the administrator, accounting agent, custodian, and transfer agent to the Fund. The Exchange states that the Adviser is not a broker-dealer, although it is affiliated with the Distributor, a broker-dealer.⁶ The Exchange represents that the Adviser has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio.⁷ According to the Exchange, the Sub-Adviser is not a broker-dealer and is not affiliated with a broker-dealer.⁸

The Exchange has made the following representations and statements in describing the Fund and its investment strategy, including the Fund’s portfolio holdings and investment restrictions.⁹

A. Exchange’s Description of the Fund’s Principal Investments

The investment objective of the Fund will be to seek current income and capital appreciation with reduced volatility over time. The Fund will seek to achieve its investment objective primarily by investing in a portfolio of “high yield” debt securities of U.S. companies. Under normal market conditions,¹⁰ the Fund will hold long

positions in high yield debt securities selected because the Sub-Adviser believes they are likely to outperform the market over time or increase in value in the near term (“Long Position”), and will hold short positions in high yield debt securities selected because the Sub-Adviser believes they are likely to lose value in the near or longer term (“Short Position”).

The Fund will not have any portfolio maturity limitation and may invest its assets in instruments with short-term, medium-term, or long-term maturities. Issuers of securities in which the Fund expects to invest will include large and medium capitalization companies, and may include small capitalization companies. According to the Exchange, the Sub-Adviser expects the Fund’s investment portfolio to include up to 200 different securities positions with a target portfolio net exposure (the market value of the Long Position minus the market value of the Short Position) of between -20% and 100%.¹¹

In selecting securities for the Fund’s portfolio, the Sub-Adviser generally will analyze debt securities included in the Bloomberg USD Corporate High Yield Bond Index. While the Fund may invest directly in high yield debt securities, the Sub-Adviser may also implement the Fund’s strategy by investing in exchange-traded pools (which will consist of exchange-traded funds, exchange-traded notes, or closed-end funds, each of which will be listed for trading on a U.S. exchange, collectively, “ETPs”) that invest a significant portion of their portfolios in high yield debt instruments (“High Yield ETPs”).

Positions in high-yield debt securities also may include foreign debt securities traded on U.S. or foreign exchanges or in U.S. or foreign over-the-counter markets, which may be denominated in foreign currencies. Any currency hedging will be accomplished by taking long or short positions in ETPs.

The Exchange states that “high yield debt securities” generally include debt securities that are rated lower than “BBB-” by Standard & Poor’s Ratings Group or “Baa3” by Moody’s Investors Service, Inc. or at a similar level by another nationally recognized statistical rating organization, or are unrated but are deemed to be of comparable quality

absence of adverse market, economic, political or other conditions, including extreme volatility or trading halts in the fixed income or other securities 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.

¹¹ See Notice, *supra* note 3, 80 FR at 51633.

by the Sub-Adviser.¹² These securities will consist of: (a) Senior and subordinated corporate debt obligations (bonds, debentures, notes, and commercial paper); (b) senior bank loans (including through loan assignments and loan participations); (c) preferred stocks; (d) municipal bonds; (e) convertible bonds; and (f) convertible preferred stocks.¹³ The Fund will not invest in other types of high-yield debt securities, such as asset-backed securities. The Fund will not be limited to investing in high-yield securities, so any of the securities listed may also be investment grade. In addition, the Fund may invest in U.S. treasuries.

According to the Exchange, as a result of its trading strategy, the Fund expects to engage in frequent portfolio transactions that will likely result in higher portfolio turnover than other similar investment companies.¹⁴ Under normal circumstances, the anticipated annual portfolio turnover rate for the Fund is expected to be greater than 100%.

B. Exchange’s Description of the Fund’s Other Investments

In addition to investing in High Yield ETPs, the Fund may invest in other fixed-income ETPs, but the Fund will not invest in leveraged ETPs. The Exchange states that the Fund will not purchase more than 3% of an ETF’s outstanding shares unless: (i) The ETF or the Fund has received an order for exemptive relief from the 3% limitation from the Commission that is applicable to the Fund; and (ii) the ETF and the Fund take appropriate steps to comply with any conditions in such order.¹⁵

The Fund also may invest in warrants.¹⁶ In certain adverse market, economic, political, or other conditions, the Fund

¹² See *id.*

¹³ The Exchange states that convertible bonds and convertible preferred stocks in which the Fund may invest, and the equity securities into which these securities may be converted, and also preferred stocks (non-convertible) in which the Fund may invest, generally will be exchange-traded. According to the Exchange, the Sub-Adviser’s current expectation is that at least 80% of these securities will be exchange-traded. The Exchange represents that at least 90% of these exchange-traded securities will be traded on exchanges that are Intermarket Surveillance Group (“ISG”) members. See *id.* at 51633 n.12.

¹⁴ See *id.* at 51633.

¹⁵ See *id.*

¹⁶ The Exchange states that warrants in which the Fund invests, and the equity securities into which these warrants may be converted, generally will be exchange-traded. According to the Exchange, the Sub-Adviser’s current expectation is that at least 80% of these securities will be exchange-traded. The Exchange represents that at least 90% of these exchange-traded securities will be traded on exchanges that are ISG members. See Notice, *supra* note 3, 80 FR at 51633 n.13.

⁵ See Post-Effective Amendment No. 40/41 to Form N-1A Registration Statement for the Trust, dated May 4, 2015 (File Nos. 333-187668 and 811-22819).

⁶ See Notice, *supra* note 3, 80 FR at 51632.

⁷ See *id.*

⁸ In the event (a) the Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer or registers as a broker-dealer, or (b) any new adviser or new sub-adviser is a registered broker-dealer or is or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the Fund portfolio and will be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding such portfolio.

⁹ The Commission notes that additional information regarding the Fund, the Trust, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, calculation of net asset value (“NAV”), distributions, and taxes, among other things, can be found in the Notice and the Registration Statement, as applicable. See Notice and Registration Statement, *supra* notes 3 and 5, respectively.

¹⁰ The term “under normal market conditions” as used herein includes, but is not limited to, the

may temporarily depart from its normal investment policies and strategy, provided that the alternative is consistent with the Fund's investment objective and is in the best interest of the Fund. At such times, the Fund may invest in cash or cash equivalents, such as money market instruments,¹⁷ and to the extent permitted by applicable law and the Fund's investment restrictions, the Fund may invest in shares of money market mutual funds. Under such circumstances, the Fund may invest up to 100% of its assets in these investments and may do so for extended periods of time. Under normal circumstances, however, the Fund may also hold money market instruments and/or shares of money market mutual funds for various reasons including to provide for funds awaiting investment, to accumulate cash for anticipated purchases of portfolio securities, to allow for shareholder redemptions, and to provide for the Fund's operating expenses.

C. Exchange's Description of the Fund's Investment Restrictions

According to the Exchange, the Fund anticipates investing entirely in fully liquid assets, but it has the flexibility to invest up to 15% of its net assets in illiquid securities and other illiquid assets.¹⁸ Under the supervision of the Board of Trustees of the Trust ("Trust Board"), the Sub-Adviser will determine the liquidity of the Fund's investments, and through reports from the Sub-Adviser, the Trust Board will monitor investments in illiquid instruments.¹⁹ The Exchange represents that, if through a change in values, net assets, or other circumstances, the Fund were in a position where more than 15% of its net assets were invested in illiquid securities or other illiquid assets, it would seek to take appropriate steps to protect liquidity.²⁰

The Fund will generally seek to invest in high-yield debt securities, bank loans,

¹⁷ The Exchange states that the money market instruments in which the Fund may invest are short-term (less than one-year) notes issued by (i) the U.S. government, (ii) an agency of the U.S. government, or (iii) a U.S. corporation. See *id.* at 51633 n.14.

¹⁸ See *id.* at 51633–34.

¹⁹ According to the Exchange, in determining the liquidity of the Fund's investments, the Sub-Adviser may consider various factors including: (i) The frequency of trades and quotations; (ii) the number of dealers and prospective purchasers in the marketplace; (iii) dealer undertakings to make a market; (iv) the nature of the security (including any demand or tender features); and (v) the nature of the marketplace for trades (including the ability to assign or offset the Fund's rights and obligations relating to the investment). See Notice, *supra* note 3, 80 FR at 51634.

²⁰ See *id.*

and other debt issuances that the Sub-Adviser deems to be liquid, with readily available prices. The Fund will only invest in bank loans that have a par amount outstanding of U.S. \$100 million or greater at the time the loan is originally issued. The Fund will not enter into a long or short position in high yield debt securities with a par amount outstanding of less than U.S. \$100 million at the time of issuance of such high yield debt securities, if upon establishing such position, the total value of such positions would represent fifty percent or greater of the Fund's net assets.

The Fund will not invest more than 25% of the value of its total assets in securities of issuers in any particular industry.

The Fund's investments (including investments in ETPs) will not be utilized to seek to achieve a leveraged return on the Fund's net assets. The Exchange represents that the Fund will not invest in futures contracts, options, swaps, or other derivative instruments.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.²¹ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,²² which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Exchange Act,²³ which sets forth the finding of Congress that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares and the exchange-traded securities held by the

²¹ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²² 15 U.S.C. 78f(b)(5).

²³ 15 U.S.C. 78k-1(a)(1)(C)(iii).

Fund will be available via UTP Level 1, as well as Nasdaq proprietary quote and trade services.²⁴ On each business day, before commencement of trading in Shares in the Regular Market Session²⁵ on the Exchange, the Trust will disclose on its Web site the identities and quantities of the portfolio of securities and other assets ("Disclosed Portfolio") held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the business day.²⁶ In addition, the Intraday Indicative Value, available on the NASDAQ OMX Information LLC proprietary index data service,²⁷ will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated and broadly displayed at least every 15 seconds during the Regular Market Session.²⁸ During hours when the local markets for foreign securities in the Fund's portfolio are closed, the Intraday Indicative Value will be updated at least every 15 seconds during the Regular Market Session to reflect currency exchange fluctuations.²⁹ The NAV of the Fund will be calculated by BNY and determined at the close of regular trading on the New York Stock

²⁴ See Notice, *supra* note 3, 80 FR at 51636.

²⁵ See Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 7:00 a.m. to 9:30 a.m. Eastern time; (2) Regular Market Session from 9:30 a.m. to 4:00 p.m. or 4:15 p.m. Eastern time; and (3) Post-Market Session from 4:00 p.m. or 4:15 p.m. to 8:00 p.m. Eastern time).

²⁶ Under accounting procedures to be followed by the Fund, trades made on the prior business day ("T") will be booked and reflected in NAV on the current business day ("T+1"). Notwithstanding the foregoing, portfolio trades that are executed prior to the opening of the Exchange on any business day may be booked and reflected in NAV on such business day. Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day. The daily disclosure will include for each portfolio security and other asset of the Fund the following information on the Fund's Web site (if applicable): name, ticker symbol, CUSIP number or other identifier, if any; type of holding (such as "bond," "note," "preferred stock," "ETP," "mutual fund"); quantity held (as measured by, for example, number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holdings in the Fund's portfolio. The Web site information will be publicly available at no charge.

²⁷ Currently, the NASDAQ OMX Global Index Data Service ("GIDS") is the NASDAQ OMX global index data feed service, offering real-time updates, daily summary messages, and access to widely followed indexes and Intraday Indicative Values for ETFs. The Exchange represents that GIDS provides investment professionals with the daily information needed to track or trade NASDAQ OMX indexes, listed ETFs, or third-party partner indexes and ETFs. See Notice, *supra* note 3, 80 FR at 51636, n.23.

²⁸ See *id.* at 51636.

²⁹ See *id.*

Exchange (ordinarily 4:00 p.m. Eastern time) on each day that such exchange is open.³⁰ The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information.³¹

The Exchange further states that the intra-day, executable price quotations on the high yield debt securities, bank loans, warrants, other fixed-income and convertible securities, including cash and cash equivalents, ETPs, and other assets held by the Fund will be available from major broker-dealer firms or on the exchange on which they are traded, if applicable.³² The foregoing intra-day price information is available through subscription services, such as Bloomberg and Thomson Reuters, which can be accessed by Authorized Participants and other investors. Information regarding market price and volume of the Shares is and will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

The Commission also believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Exchange states that it will obtain a representation from the issuer of the Shares that the NAV per Share will be

calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.³³ The Exchange also represents that the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Nasdaq will halt or pause trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pauses under Nasdaq Rules 4120(a)(11) and (12). Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.³⁴ Trading in the Shares also will be subject to Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.³⁵ The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees.³⁶ In addition, the Exchange states that the Adviser is not a broker-dealer, although it is affiliated with the Distributor, a broker-dealer, and that the Adviser has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio.³⁷ The Exchange states that the Sub-Adviser is

³³ See *id.*

³⁴ These may include: (1) the extent to which trading is not occurring in the securities and/or the financial instruments constituting the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. See *id.* at 51636.

³⁵ See *id.*

³⁶ See *id.* at 51637.

³⁷ See *id.* at 51632. See also *supra* note 8. The Exchange further represents that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 ("Advisers Act"). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A-1 under the Advisers Act, which requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of their relationship with their clients as well as compliance with other applicable securities laws. Accordingly, investment advisers must have procedures designed to prevent the communication and misuse of non-public information, 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 violation, 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.

not a broker-dealer and is not affiliated with a broker-dealer.³⁸ Further, the Commission notes that the Reporting Authority³⁹ that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio.⁴⁰ The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also 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.⁴¹

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq's existing rules governing the trading of equity securities. In support of this proposal, the Exchange represented that:

(1) The Shares will be subject to Nasdaq Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) Trading in the Shares will be subject to the existing trading surveillances administered by both Nasdaq and FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws, and these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to detect and help deter violations of Exchange rules and applicable federal securities laws.

(3) FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares or other exchange-traded securities with other markets and other entities that are ISG⁴² members, and FINRA, on behalf of the Exchange, may obtain trading information regarding trading in the Shares; exchange-traded fixed income securities; exchange-traded warrants; exchange-traded convertible securities; ETPs; or other exchange-traded securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares; exchange-traded warrants; exchange-traded fixed-income securities; exchange-traded convertible

³⁸ See *id.* at 51632.

³⁹ Nasdaq Rule 5730(c)(4) defines "Reporting Authority."

⁴⁰ See Nasdaq Rule 5735(d)(2)(B)(ii).

⁴¹ 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.

⁴² For a list of the current members of ISG, see www.isgportal.org.

³⁰ According to the Exchange, ETPs, exchange-traded fixed income securities, exchange-traded convertible securities, exchange-traded warrants, and any other exchange traded securities will be valued at the official closing price on their principal exchange or board of trade, or lacking any current reported sale at the time of valuation, at the mean between the most recent bid and asked quotations on the principal exchange or board of trade. Portfolio securities traded on more than one securities exchange will be valued at the last sale price or official closing price, as applicable, on the business day as of which such value is being determined at the close of the exchange representing the principal market for such securities. Fixed-income securities traded over-the-counter (including high yield fixed-income securities and money market instruments); warrants traded over-the-counter; and convertible securities traded over-the-counter will be valued at the mean between the most recent available bid and asked quotations provided by parties that make a market in the instrument. If recent bid and ask quotations are not available, these securities will be valued in accordance with the Fund's fair valuation procedures. Money market instruments with maturities of less than 60 days will be valued at amortized cost. Shares of mutual funds that are not exchange-listed will be valued at their net asset value.

³¹ See *id.* at 51638.

³² See *id.*

securities; ETPs; or other exchange-traded securities from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities, including corporate debt securities and money market instruments, held by the Fund reported to FINRA's TRACE.

(4) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(5) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (c) how and by whom information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (d) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(6) For initial and continued listing, the Fund must be in compliance with Rule 10A-3 under the Act.⁴³

(7) At least 90% of the convertible bonds, convertible preferred stocks, and warrants in which the Fund invests, and the equity securities into which these securities may be converted, and also preferred stocks (non-convertible) in which the Fund invests, will be traded on exchanges that are ISG members.

(8) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets.

(9) The Fund will only invest in bank loans that have a par amount outstanding of U.S. \$100 million or greater at the time the loan is originally issued.

(10) The Fund will not enter into a long or short position in high yield debt securities with a par amount outstanding of less than U.S. \$100 million at the time of issuance of such

high yield debt securities, if upon establishing such position, the total value of such positions would represent fifty percent or greater of the Fund's net assets. In addition, the Fund will not invest in other types of high-yield debt securities, such as asset-backed securities.

(11) The Fund will not invest more than 25% of the value of its total assets in securities of issuers in any particular industry.

(12) The Fund's investments (including investments in ETPs) will not be utilized to seek to achieve a leveraged return on the Fund's net assets.

(13) The Fund will not invest in futures contracts, options, swaps, or other derivative instruments.

(14) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.

This approval order is based on all of the Exchange's representations, including those set forth above and in the Notice. The Commission notes that the Fund and the Shares must comply with the requirements of Nasdaq Rule 5735 to be listed and traded on the Exchange.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act⁴⁴ and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,⁴⁵ that the proposed rule change (SR-NASDAQ-2015-095) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁶

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-26323 Filed 10-15-15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76127; File No. SR-NYSE-2015-36]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Approving Proposed Rule Change, Amending Section 907.00 of the Listed Company Manual (the "Manual") To (i) Amend the Suite of Complimentary Products and Services That Are Offered to Certain Current and Newly Listed Companies, (ii) Update the Value of Complimentary Products and Services Offered to Listed Companies, and (iii) Provide That Complimentary Products and Services Would Also Be Offered to Companies That Transfer Their Listing to the Exchange From Another National Securities Exchange

October 9, 2015.

I. Introduction

On August 11, 2015, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend section 907.00 of the listed company manual ("Manual") to amend the suite of complimentary products and services that are offered to certain current and newly listed companies and update the value of complimentary products and services offered to listed companies. In addition, the proposal would separate companies that transfer their listing to the Exchange from another national securities exchange to a new category and expand the complimentary products and services offered to such transfer companies. The proposed rule change was published for comment in the **Federal Register** on August 25, 2015.³ No comment letters were received in response to the Notice. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

In December 2013, the Exchange adopted a rule to expand the suite of complimentary products and services that it offers to certain current and newly listed companies on the Exchange.⁴ Under this rule, certain

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 75740 (August 19, 2015), 80 FR 51617 ("Notice").

⁴ See Securities Exchange Act Release No. 70971 (Dec. 3, 2013), 78 FR 73905 (Dec. 9, 2013) (SR-

⁴⁴ 15 U.S.C. 78f(b)(5).

⁴⁵ 15 U.S.C. 78s(b)(2).

⁴⁶ 17 CFR 200.30-3(a)(12).

⁴³ See 17 CFR 240.10A-3.

companies currently listed on the Exchange (“Eligible Current Listings”) are offered a suite of complimentary products and services that vary depending on the number of shares of common stock or other equity security that a company has outstanding. The Exchange presently offers a suite of complimentary products and services to (i) any U.S. company that lists common stock on the Exchange for the first time and any non-U.S. company that lists an equity security on the Exchange under Section 102.01 or 103.00 of the Manual for the first time, regardless of whether such U.S. or non-U.S. company conducts an offering and (ii) any U.S. or non-U.S. company emerging from a bankruptcy, spinoff (where a company lists new shares in the absence of a public offering), or carve-out (where a company carves out a business line or division, which then conducts a separate initial public offering) (collectively, “Eligible New Listings”). Currently, companies that transfer their listing to the Exchange are offered complimentary products and services on the same terms as Eligible Current Listings.

The Exchange proposes to amend Section 907.00 of the Manual to (i) amend the suite of complimentary products and services that are offered to Eligible Current Listings and Eligible New Listings, (ii) update the value of complimentary products and services offered to such companies, and (iii) provide that any U.S. or non-U.S. company that transfers its listing of common stock or equity securities, respectively, to the Exchange from another national securities exchange (“Eligible Transfer Companies”) would be eligible to receive an enhanced package of complimentary products and services comparable to the package offered to Eligible New Listings, with the exception of corporate governance tools.⁵

The Exchange proposes to update the approximate commercial value of the following offerings to Eligible Current Listings, Eligible New Listings, and Eligible Transfer Companies: Market surveillance products and services from \$45,000 to \$55,000 per annum, corporate governance tools from \$20,000 to \$50,000 per annum, web-hosting products and services from a range of \$12,000–16,000 to \$16,000 per annum, market analytics products and services from \$20,000 to \$30,000 per annum, and

news distribution products and services from \$10,000 to \$20,000 per annum. The Exchange also proposes to include web-casting services (with a commercial value of approximately \$6,500 annually) as a separate category of complimentary products and services offered to certain issuers.⁶ In addition, the Exchange proposes to add whistleblower hotline services (with a commercial value of approximately \$4,000 annually) to the list of services that it offers to all listed companies for a period of 24 months. The whistleblower hotline services will replace data room services and virtual investor relation tools (with a commercial value of \$15,000–\$20,000) as complimentary products offered to all listed issuers.

Currently, all listed issuers receive some complimentary products and services through NYSE Market Access Center. The Exchange also offers Eligible Current Listings a suite of products and services, varying based on the number of shares such companies have issued and outstanding. Eligible Current Listings that have at least 270 million shares issued and outstanding (“Tier One Eligible Current Listing”) are presently offered (i) a choice of market surveillance, corporate governance tools and advisory services or market analytics products and services and (ii) web-hosting products and services, on a complimentary basis. Eligible Current Listings that have between 160 million and up to 270 million shares issued and outstanding (“Tier Two Eligible Current Listing”) are presently offered a choice of market analytics, corporate governance tools, or web-hosting products and services. The Exchange proposes to amend Section 907.00 to delete corporate governance tools and advisory services from the suite of products offered to a Tier One Eligible Current Listing and corporate governance tools from the suite of products offered to a Tier Two Eligible Current Listing. In both cases, the proposed rule replaces the deleted service with web-casting products and services.

The Exchange currently offers Eligible New Listings different products and services based on such companies’ global market value. Eligible New Listings with a global market value of \$400 million or more (each a “Tier A Eligible New Listing”) are presently offered web-hosting and news

distribution products and services for a period of 24 months and either (i) market surveillance products and services for a period of 12 calendar months from the date of listing or (ii) a choice of market analytics products and services or corporate governance tools for a period of 24 calendar months from the date of listing. Eligible New Listings with a global market value of less than \$400 million (each a “Tier B Eligible New Listing”) are presently offered web-hosting and news distribution products and services for a period of 24 months from the date of listing. The Exchange proposes to amend Section 907.00 to offer 24 months each of market analytics, market surveillance products, web-hosting, web-casting, corporate governance tools, and news distribution products and services to Tier A Eligible New Listings. Accordingly, the Exchange proposes to delete text from Section 907.00 that discusses providing market surveillance products and services for only 12 months, as well as the option for continuing such services at the end of the initial 12 month period. The proposed rule further amends Section 907.00 to offer 24 months of web-casting, market analytics, and corporate governance tools to Tier B Eligible New Listings, in addition to the currently-offered web-hosting and news distribution products.

Pursuant to the proposed rule change, Eligible Transfer Companies would be offered a package of complimentary products and services that are similar to Eligible New Listings, with one exception.⁷ The one difference between the packages is that the Exchange will not offer corporate governance tools to Eligible Transfer Companies, while Eligible New Listings will receive this service.

Regarding the timing of complimentary products and services, the proposed rule amends Section 907.00 to specify that if an Eligible New Listing or Eligible Transfer Company

⁷ As noted above, the Exchange proposes to offer Eligible Transfer Companies a package of complimentary products and services comparable to the package that it offers to Eligible New Listings. Therefore, the Exchange proposes to utilize the same metric, *i.e.*, global market value, to determine eligibility for each designation so as to avoid confusion. Currently, transfer companies may receive complimentary products and services if they qualify to be designated as an Eligible Current Listing, such designation being based on the number of outstanding shares of a company’s equity securities. Under the proposed rule change, Eligible Transfer Companies with a global market value of \$400 million or more will be eligible to receive a suite of complimentary products and services valued at \$127,500 per year for two years and Eligible Transfer Companies with a global market value of less than \$400 million will be eligible to receive a suite of complimentary products and services valued at \$72,500 per year for two years.

NYSE–2013–68) (“December 2013 Approval Order”).

⁵ Eligible transfers currently receive complimentary products and services, if eligible, under the “currently listed issuers” category.

⁶ The web-hosting product offered by the Exchange provides eligible issuers with a Web site containing business content that can be viewed by investors. Web-casting services enable companies to host interactive web-casts to communicate with investors. Eligible companies will receive four interactive web-casts each year.

begins using a particular service within 30 days after the date of listing, the complimentary period begins on such date of first use. In all other instances, the complimentary period begins on the listing date.

In addition to the foregoing, the Exchange proposes making several changes to its rule to reflect a change in terminology. The proposed rule change amends Section 907.00 to change the terms “newly listed issuer” and “currently listed issuers” to “Eligible New Listing” and “Eligible Current Listings,” respectively. The Exchange also proposes to amend Section 907.00 to include a definition of Eligible Transfer Companies.⁸ Accordingly, since Eligible Transfer Companies would be a separate category of issuer under the proposed rule, the Exchange stated in its filing that it does not believe there could be any inference that a transfer company would be included in the definition of an Eligible New Listing. Therefore, the Exchange proposes to delete the exception for companies that are transferring their listing from another national securities exchange from the current definition of newly listed issuers, which would be renamed Eligible New Listing under the proposed rule.

The Exchange also proposes to amend the first paragraph of Section 907.00 of the Manual to specify that it will offer certain complimentary products and services, and access to discounted third-party products and services through the NYSE Market Access Center to both currently and newly listed issuers, whereas previously it stated such services were only offered to currently listed issuers.

While the Exchange will implement the proposed rule upon approval, any Eligible New Listing that listed on the Exchange prior to approval of the proposed rule will continue to receive services under the terms of the current rule. Therefore, for as long as any Eligible New Listing is receiving services under the terms of Section 907.00 of the Manual as currently in effect, the Exchange will maintain a link to such section in the Introductory Note to Section 907.00.

With respect to Eligible Current Listings, to the extent that the Exchange has already paid a third-party provider (prior to approval) for corporate governance services to an Eligible Current Listing, such complimentary

service will continue until the payments run out. Once any pre-approval payments run out, such services will be discontinued. The Exchange expects all corporate governance services to Eligible Current Listings to be completely discontinued no later than early 2016.

The specific products and services offered by the Exchange will be developed by the Exchange or by third-party vendors. In its filing, the Exchange represented that NYSE Governance Services⁹ will offer and develop the corporate governance tools, but will not provide any other service related to the proposed rule. NYSE Governance Services is an entity that is owned by the Exchange’s parent company that provides corporate governance, risk and compliance services to its clients, including companies listed on the Exchange. According to the Exchange, companies that are offered these products are under no obligation to accept them and a company’s listing on the Exchange is not conditioned upon acceptance of any product or service. Moreover, the Exchange represents that, from time to time, companies elect to purchase products and services from other vendors at their own expense rather than accepting comparable products and services offered by the Exchange.

III. Discussion and Commission Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act.¹⁰ Specifically, the Commission finds that the proposal is consistent with Sections 6(b)(4)¹¹ and (5) of the Act¹² in particular, in that the proposed rule is designed to provide for the equitable

⁹ In its filing, NYSE stated its belief that NYSE Governance Services is not a “facility” of the Exchange as defined in 15 U.S.C. 78c(a)(2), and noted that its proposed rule change is being filed with the Commission under Section 19(b)(2) of the Act because it relates to services offered in connection with a listing on the Exchange. See Notice *supra* note 3. The Commission notes that the definition of a “facility” of an exchange is broad under the Act, and “includes its premises, tangible or intangible property whether on the premises or not, any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange . . . and any right of the exchange to the use of any property or service.” The Commission further notes that any determination as to whether a service or other product is a facility of an exchange requires an analysis of the particular facts and circumstances.

¹⁰ 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹¹ 15 U.S.C. 78f(b)(4).

¹² 15 U.S.C. 78f(b)(4) and (5).

allocation of reasonable dues, fees, and other charges among Exchange members, issuers, and other persons using the Exchange’s facilities, and is not designed to permit unfair discrimination between customers, issuers, brokers or dealers. Moreover, the Commission believes that the proposed rule change is consistent with 6(b)(8) of the Act¹³ in that it does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

As described above, the Exchange proposes to alter the complimentary products and services it offers companies. Specifically, the Exchange proposes to (i) remove corporate governance tools and advisory services for Tier One companies, (ii) remove corporate governance tools for Tier Two companies, (iii) expand the services provided to Tier A Eligible New Listings to include all of the services listed, as described above, for a period of 24 months, not just provide a choice of services, (iv) expand the services provided to Tier B Eligible New Listings to include market analytics and corporate governance tools, (v) offer Eligible Transfer Companies the same products and services offered to Eligible New Listings, except for corporate governance tools,¹⁴ (vi) provide web-casting to Tier One, Tier Two, Tier A, and Tier B companies, and (vii) replace data room services and virtual investor relation tools available to all issuers annually with a whistleblower hotline for a period of 24 months.

The Commission believes that it is consistent with the Act for the Exchange to revise the products and services it offers to companies. The Exchange has represented that the corporate governance services are not as helpful to more established companies as they are to newly listed companies and that web-casting may be more useful to them.¹⁵ According to the Exchange, the corporate governance products currently offered to Eligible Current Listings are in low demand. The Exchange believes replacing such offerings with web-casting would be more beneficial to listed companies who utilize this service in connection with quarterly earnings releases. The Commission believes that, based on NYSE’s representations, replacing a little-

¹³ 15 U.S.C. 78f(b)(8).

¹⁴ Because the Exchange is proposing to offer Eligible Transfer Companies a package of complimentary benefits similar to the benefits offered to Eligible New Listings, the Exchange also proposes using the same metric, *i.e.*, global market value, to determine eligibility for certain products and services.

¹⁵ See Notice, *supra* note 3.

⁸ For purposes of this Section 907.00, the term “Eligible Transfer Company” means any U.S. or non-U.S. company that transfers its listing of common stock or equity securities, respectively, to the Exchange from another national securities exchange.

utilized service by companies already listed with one that could help companies communicate better with shareholders is reasonable and consistent with Section 6(b)(5) of the Act.

In addition, the Exchange believes that it is appropriate to expand the suite of complimentary products and services it offers to Tier A and Tier B Eligible New Listings, because such companies are listing on the Exchange for the first time and frequently have greater needs with respect to developing their corporate governance and shareholder outreach capabilities.¹⁶ Moreover, the Exchange has represented that it faces competition in the market for listing services.¹⁷ As part of this competition, the Exchange seeks to entice Nasdaq-listed companies to transfer their listing to the Exchange. The Exchange competes in part by improving the quality of the services that it offers to listed companies. NYSE believes that offering transfers from Nasdaq a similar package to that currently offered to NYSE listed companies transferring to Nasdaq, as well as new listings on Nasdaq, should enhance its ability to compete for listings. According to the Exchange, by offering products and services on a complimentary basis and ensuring that it is offering the services most valued by its listed issuers, it improves the quality of the services that listed companies receive.¹⁸

Accordingly, the Commission believes that the proposed rule reflects the current competitive environment for exchange listings among national securities exchanges, and is appropriate and consistent with Section 6(b)(8) of the Act.¹⁹ Further, by extending the provision of certain complementary services (as listed above) to Tier A and Tier B Eligible New Listings to 24 months and by entitling Eligible Transfer Companies to receive these products and services, other than corporate governance tools, on similar terms as Eligible New Listings, the proposed change enables the Exchange to better compete for new listings.

Moreover, the Commission believes that it is appropriate for the Exchange to offer varying services to different categories of issuers. The Commission has previously found that the tiers originally established under the corporate products and services rule was consistent with the Act.²⁰ The

Commission further found that the changes approved in the December 2013 Approval Order expanding the complimentary products and services offered to some tiers but not others was also justified, in part, based on the different-sized companies within each tier and the amount of services they needed.²¹ According to the Exchange, the current proposal to expand the products and services available to Tier A and Tier B Eligible New Listings should ease the transition of companies becoming public for the first time.²² In addition, as stated by the Exchange, it competes with Nasdaq for listings and further, that Nasdaq offers similar products and services to new listings, including transfers.²³

As noted above, under the proposal, while newly listed companies and transfers will receive similar services there is one exception involving corporate governance tools (valued at \$50,000) which newly listed companies will receive but not transfers. NYSE argues that this approach is consistent with the changes being proposed for currently listed companies in that in the Exchange's experience these tools are not as useful for already established companies and as a result are in low demand by such listed companies. Based on these representations, the Commission does not believe that the exception for transfers violates the unfair discrimination standard under Section 6(b)(5) of the Act and appears to provide equal treatment among established companies, whether currently listed or transferring. The Commission notes that all listed companies will continue to receive some level of free services, including the addition of the whistleblower hotline services being approved in this order. The Commission also notes that within each tier all issuers receive the exact same package of services. The approval of this proposal, including the updated dollar values and specific services provided within each tier, will therefore help to ensure that individual listed companies are not given specially

negotiated packages of products and services to list or remain listed which would raise unfair discrimination issues under the Act. The Commission also believes that it is reasonable, and in fact required by Section 19(b) of the Act, that the Exchange amend its rule to update the commercial values of the products it offers to Eligible Current Listings, Eligible Transfer Companies, and Eligible New Listings.²⁴ This provides greater transparency to Exchange's rules and the fees, and the value of free products and services, applicable to listed companies.

The Commission also believes that it is consistent with the Act for the Exchange to allow the complimentary period for a particular service offered to Eligible New Listings and Eligible Transfer Companies to begin on the date of first use if a company begins to use the service within 30 days after the date of listing. According to the Exchange, companies listing on the Exchange for the first time often require a period of time after listing to complete the contracting and training process with vendors providing the complimentary products and services.²⁵ Therefore, many companies are not able to begin using the suite of products offered to them immediately on the date of listing.²⁶ The Commission notes that this proposed change is substantially similar to Nasdaq Rule IM-5900-7, which also allows a company to begin using services within 30 days of listing.²⁷ As noted in the Nasdaq Order, the Commission believes that this change would provide only a short window of additional time to allow companies to finalize their contracts for the complimentary products and services, and that this additional time would only be available to companies that have already determined to list on the Exchange.²⁸

Based on the factors noted above, the Commission continues to believe that NYSE's products and services, and their commercial value, are equitably allocated among issuers, consistent with Section 6(b)(4) of the Act.²⁹ The

NYSE-2011-20) ("Approval Order"). In particular, the Approval Order states that while not all issuers receive the same level of services, NYSE has stated that trading volume and market activity are related to the level of services that the listed companies would use in the absence of complimentary arrangements. The Commission found, among other things, that ". . . the products and services and their commercial value are equitably allocated among issuers consistent with Section 6(b)(4) of the Act, and the rule does not unfairly discriminate between issuers consistent with Section 6(b)(5) of the Act." See Approval Order, 76 FR at 51452.

²¹ See December 2013 Approval Order, *supra* note 4.

²² See Notice, *supra* note 3.

²³ See *id.*

²⁴ We would expect the Exchange, consistent with Section 19(b) of the Act, to periodically update the value of products and services offered should they change. This would help to provide transparency to listed companies on the value of the free services they receive and the actual costs associated with listing on the Exchange.

²⁵ See Notice, *supra* note 3.

²⁶ See *id.*

²⁷ See Securities Exchange Act Release No. 72669 (July 24, 2014), 79 FR 44234 (July 30, 2014) (approving Nasdaq-2014-058) ("Nasdaq Order").

²⁸ The Commission expects the Exchange to track the start (and end) date of each free service.

²⁹ 15 U.S.C. 78f(b)(4).

¹⁶ See *id.*

¹⁷ See *id.*

¹⁸ See *id.*

¹⁹ 15 U.S.C. 78f(b)(8).

²⁰ See Securities Exchange Act Release No. 65127 (Aug. 12, 2011), 76 FR 51449 (Aug. 18, 2011) (SR-

Commission also continues to believe that the rule does not unfairly discriminate between issuers, consistent with Section 6(b)(5) of the Act.³⁰ Finally, the Commission believes that the proposal does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, consistent with Section 6(b)(8) of the Act.³¹

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³² that the proposed rule change (SR-NYSE-2015-36), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³³

Brent J. Fields,
Secretary.

[FR Doc. 2015-26336 Filed 10-15-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76120; File No. SR-BATS-2015-83]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

October 9, 2015.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 1, 2015, BATS Exchange, Inc. (the “Exchange” or “BATS”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act ³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members ⁵ and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange’s Web site at www.batstrading.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the fee schedule applicable to the Exchange’s options platform (“BATS Options”) effective immediately, in order to: (i) Increase the fees for certain logical ports; and (ii) provide for separate fees based upon the number of logical ports utilized.

A logical port represents a port established by the Exchange within the Exchange’s system for trading and billing purposes. Each logical port established is specific to a Member or non-member and grants that Member or non-member the ability to operate a specific application, such as FIX order entry or PITCH data receipt. The Exchange’s Multicast PITCH data feed is available from two primary feeds, identified as the “A feed” and the “C feed”, which contain the same information but differ only in the way such feeds are received. The Exchange also offers two redundant feeds,

identified as the “B feed” and the “D feed.” The Exchange also offers a bulk-quoting interface which allows Users ⁶ of BATS Options to submit and update multiple bids and offers in one message through logical ports enabled for bulk-quoting.⁷ The bulk-quoting application for BATS Options is a particularly useful feature for Users that provide quotations in many different options.

Logical ports, including Multicast PITCH Spin Server and GRP ports, which are used to request and receive a retransmission of data from the Exchange, are currently subject to a fee of \$400 per month per port and ports with bulk quoting capabilities are charged \$1,500 per month per port. These fees are set and do not currently vary based on the number of ports purchased. In addition, logical port fees are limited to logical ports in the Exchange’s primary data center and no logical port fees are assessed for redundant secondary data center ports. The Exchange assesses the monthly per logical port fees for all of a Member and non-Member’s logical ports.

The Exchange now proposes to increase the fees for logical ports (including Multicast PITCH Spin Server and GRP ports) from \$400 per port per month to \$550 per port per month for the first five ports. Multicast PITCH Spin Server Ports and GRP Ports would now be subject to a fee of \$550 per month for a set of primary ports (A or C feed). The Exchange will continue to offer for free the ports necessary to receive the Exchange’s redundant Multicast “B feed” and “D feed”, as well as all ports made available in the Exchange’s secondary data center. Accordingly, this proposal only applies to ports used to receive an Exchange primary Multicast PITCH feeds at the Exchange’s primary data center. Other than as described below, the Exchange does not propose to amend the monthly fee for ports with bulk quoting capabilities.

Where a User subscribes to more than five ports, the Exchange proposes to charge for each port in excess of five \$650 per logical port per month and \$2,000 per month for logical ports with bulk quoting capabilities. For example, if a User subscribes to seven logical ports, it would pay \$550 per port per month for ports one through five and

⁶ A User on BATS Options is either a member of BATS Options or a sponsored participant who is authorized to obtain access to the Exchange’s system pursuant to BATS Rule 11.3.

⁷ See Securities Exchange Act Release Nos. 65133 (August 15, 2011), 76 FR 52032 (August 19, 2011) (SR-BATS-2011-029) and 65307 (September 9, 2011), 76 FR 57092 (September 15, 2011) (SR-BATS-2011-034).

⁵ The term “Member” is defined as “any registered broker or dealer that has been admitted to membership in the Exchange.” See Exchange Rule 1.5(n).

³⁰ 15 U.S.C. 78f(b)(5).

³¹ 15 U.S.C. 78f(b)(8).

³² 15 U.S.C. 78s(b)(2).

³³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

\$650 per port per month for ports six and seven. Except for bulk quoting ports, which will be separately evaluated, the Exchange will sum logical ports across all classifications in order to determine applicable fees. For example, if a User subscribes to five logical ports and one logical port with bulk quoting capabilities, that User would be charged \$550 per port per month for each logical port and \$1,500 per month for the port with bulk quoting capabilities. That User would not be charged the increased fees for its sixth ports. However, should that User subscribe to six logical ports and one logical port with bulk quoting capabilities, that User would be charged \$550 per port per month for logical ports one through five, \$650 per month for its sixth logical port, and \$1,500 per month for the port with bulk quoting capabilities.

Implementation Date

The Exchange proposes to implement these amendments to its fee schedule effective immediately.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.⁸ Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,⁹ in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls.

The Exchange operates in a highly competitive market in which exchanges offer connectivity services as a means to facilitate the trading activities of members and other participants. Accordingly, fees charged for connectivity are constrained by the active competition for the order flow of such participants as well as demand for market data from the Exchange. If a particular exchange charges excessive fees for connectivity, affected members will opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, the exchange charging

excessive fees would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it by affected members, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

The Exchange believes that the proposal to increase fees for logical ports is equitably allocated, reasonable, and not unfairly discriminatory in that the proposal will help the Exchange to cover increasing infrastructure costs associated with offering and maintaining logical ports connections. The Exchange notes its proposal to increase the fee for logical ports equals that currently charged by the New York Stock Exchange, Inc. ("NYSE") and NYSE Arca, Inc. ("NYSE Arca").¹⁰ In addition, the Exchange believes that charging different fees based on the number of ports a User subscribes to is also equitably allocated, reasonable, and not unfairly discriminatory because proposed fees based on the number of ports subscribed to would encourage Users to become more efficient with, and reduce the number of ports used, thereby resulting in a corresponding increase in the efficiency that the Exchange would be able to realize with respect to managing its own infrastructure. Lastly, the Exchange notes that the NYSE and NYSE Arca also previously charged different fees based on the number of ports subscribed to.¹¹

Lastly, the Exchange also believes that the proposed amendments to its fee schedule are non-discriminatory because they will apply uniformly to all Members. All Members that voluntarily select various service options will be charged the same amount for the same services. All Members have the option to select any connectivity option, and there is no differentiation among Members with regard to the fees charged for the services offered by the Exchange.

¹⁰ See File Nos. SR-NYSE-2015-43 (filed September 23, 2015), and SR-NYSEArca-2015-87 (filed September 22, 2015) (proposing a fee of \$550 per port per month). In addition, the charge on the NASDAQ Stock Market LLC ("NASDAQ") for a FIX Trading Port is \$550 per port per month. See NASDAQ Rule 7015. A separate charge for Pre-Trade Risk Management ports also is applicable, which ranges from \$400 to \$600 and is capped at \$25,000 per firm per month. See NASDAQ Rule 7016.

¹¹ See File Nos. SR-NYSE-2015-43 (filed September 23, 2015), and SR-NYSEArca-2015-87 (filed September 22, 2015).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed amendments to its fee schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. Further, excessive fees for connectivity, including logical port fees, would serve to impair an exchange's ability to compete for order flow rather than burdening competition. The Exchange also does not believe the proposed rule change would impact intramarket competition as it would apply to all Members and non-Members equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹² of the Act and subparagraph (f)(2) of Rule 19b-4¹³ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 17 CFR 240.19b-4(f)(2).

⁸ 15 U.S.C. 78f.

⁹ 15 U.S.C. 78f(b)(4).

Commission shall institute proceedings under Section 19(b)(2)(B)¹⁴ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File No. SR-BATS-2015-83 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File No. SR-BATS-2015-83. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-BATS-

2015-83, and should be submitted on or before November 6, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-26328 Filed 10-15-15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76124; File No. SR-NYSEArca-2015-91]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Amendment No. 1, Amending the Exchange's Fee Schedule To Eliminate the Sponsor Fee In Connection With Listing a New Derivative Securities Product on the Exchange

October 9, 2015.

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 October 5, 2015, 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, II, and III below, which Items have been prepared by the self-regulatory organization. On October 8, 2015, the Exchange filed Amendment No. 1 to the proposed rule change.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Schedule of Fees and Charges ("Fee Schedule") to eliminate the \$20,000 one-time consultation fee when a first time sponsor, managing owner, general partner or equivalent is listing a new Derivative Securities Product on the Exchange. 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,

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ In Amendment No. 1, the Exchange represented that, notwithstanding the elimination of the Sponsor Fee (as defined herein), the Exchange will continue to be able to fund its regulatory obligations.

and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange's Schedule of Fees and Charges ("Schedule") provides that, where a first time sponsor, managing owner, general partner or equivalent ("Sponsor") lists a new Derivative Securities Product⁵ on the Exchange, the Sponsor is charged a one-time consulting charge of \$20,000 (the "Sponsor Fee"). The Exchange originally implemented the Sponsor Fee in 2009 to adequately compensate the Exchange for additional legal and business resources to properly advise new Sponsors through the listing process.⁶

The Exchange proposes to amend the Fee Schedule to eliminate the Sponsor Fee. The Exchange has determined to eliminate the Sponsor Fee to permit the Exchange to better compete for listings of Derivative Securities Products with other exchanges that do not impose a fee similar to the Sponsor Fee. Elimination of the Sponsor Fee would benefit Sponsors by providing a cost savings and by permitting them to select their listing venue for a new Derivative Securities Product based on level of service and without consideration of

⁵ For the purposes of the Schedule, the term "Derivative Securities Products" includes securities described in NYSE Arca Equities Rules 5.2(j)(3) (Investment Company Units); 8.100 (Portfolio Depository Receipts); 8.200 (Trust Issued Receipts); 8.201 (Commodity-Based Trust Shares); 8.202 (Currency Trust Shares); 8.203 (Commodity Index Trust Shares); 8.204 (Commodity Futures Trust Shares); 8.300 (Partnership Units); 8.500 (Trust Units); 8.600 (Managed Fund Shares), and 8.700 (Managed Trust Securities).

⁶ See Securities Exchange Act Release No. 60184 (June 29, 2009), 74 FR 32209 (July 7, 2009) (SR-NYSEArca-2009-52) (notice of filing of proposed rule change to amend the schedule of fees and changes for Exchange services).

¹⁴ 15 U.S.C. 78s(b)(2)(B).

whether a consulting fee would be charged.

Listing Fees and Annual Fees applicable to Derivatives Securities Products would remain unchanged.

2. Statutory Basis

NYSE Arca believes that the proposal is consistent with Section 6(b)⁷ of the Act, in general, and Section 6(b)(4)⁸ of the Act in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its issuers and other persons using its facilities. In addition, the Exchange believes the proposal is consistent with the requirement under Section 6(b)(5)⁹ 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 of a free and open market and, in general, to protect investors and the public interest. The proposed elimination of the Sponsor Fee is equitable and does not unfairly discriminate between issuers because it would apply uniformly to all Sponsors. The Exchange believes elimination of the Sponsor Fee is reasonable in that it constitutes a reduction in fees for Sponsors. Notwithstanding the elimination of the Sponsor Fee, the Exchange will continue to be able to fund its regulatory obligations.

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 purpose of the Act. The Exchange believes the proposed rule change would promote competition because it will permit the Exchange to better compete with other exchanges that do not charge a fee similar to the Sponsor Fee.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁰ of the Act and

subparagraph (f)(2) of Rule 19b-4¹¹ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹² of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, 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-2015-91 on the subject line.

Paper comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSEArca-2015-91. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public

Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from the submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2015-91 and should be submitted on or before November 6, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-26324 Filed 10-15-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76123; File No. SR-NASDAQ-2015-096]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Approving Proposed Rule Change To Adopt a Kill Switch for NOM

October 9, 2015.

I. Introduction

On August 7, 2015, The NASDAQ Stock Market LLC filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt a risk protection functionality referred to as a kill switch that will be available to all Participants of the NASDAQ Options Market ("Exchange" or "NOM"). The proposed rule change was published for comment in the **FEDERAL REGISTER** on August 26, 2015.³ The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to offer to all its members a new optional risk protection functionality for options to

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 75743 (August 26, 2015), 80 FR 51850 ("Notice").

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(4).

⁹ 15 U.S.C. 78f(b)(5).

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f)(2).

¹² 15 U.S.C. 78s(b)(2)(B).

help members control their quote and order activity on NOM.⁴ Referred to as a “Kill Switch,” the functionality will allow NOM Participants to remove quotes and cancel open orders, and will prevent the submission of new quotes and orders until the Exchange re-enables access to the NOM System for the Participant.⁵

To use the Kill Switch, a Participant will send a message⁶ to the NOM System to: (i) Promptly remove quotes; and/or (ii) promptly cancel orders for certain specified Identifiers (e.g., a particular Exchange account, port, or badge or mnemonic, or for a group of Identifiers).⁷ The Exchange’s proposal does not allow Participants to remove quotes or cancel orders by symbol. The NOM System will send an automated message to the Participant when it has processed a Kill Switch request.

The NOM Participant will be unable to enter any new quotes or orders using the affected Identifier(s) until the Participant makes a verbal request to the Exchange and Exchange staff enables re-entry. Once enabled for re-entry, the Exchange will send a message to the Participant and, if it requests to receive such notifications, to the Participant’s clearing firm as well.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,⁸ and, in particular, the requirements of Section 6 of the Act.⁹ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,¹⁰ which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and

equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and that the rules are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

According to the Exchange, the proposed rule change is designed to protect Participants in the event that the Participant encounters a situation, like a systems issue, for which they would like to withdraw temporarily from the market.¹¹ The Exchange further notes that the proposed Kill Switch is designed to increase systemic protections and, in so doing, should encourage liquidity generally while removing impediments to market participation.¹² To the extent that the Exchange’s proposal provides member firms with greater control over their quotes and orders, and allows firms to remove quotes and cancel orders in an appropriate manner, then the proposal may encourage firms to provide liquidity on NOM and thus contribute to fair and orderly markets in a manner that protects the public interest, protects investors, and is not designed to permit unfair discrimination.

Further, the Commission agrees that it would be appropriate to notify a Participant’s clearing member, at the clearing member’s request, once a Participant’s selected Identifiers are re-enabled following the Participant’s use of the Kill Switch. Because the clearing member accepts financial responsibility for clearing the Participant’s trades, notifying the applicable clearing member of a Participant’s re-enabled Identifiers following use of the Kill Switch may be appropriate and help the clearing member manage the risk associated with the Participant’s trading activity.

The Commission notes that the Exchange represented in its proposal that the Kill Switch will operate consistently with a broker-dealer’s firm quote obligations pursuant to Rule 602 of Regulation NMS,¹³ and that the proposal does not diminish a market-maker’s obligation to provide continuous two-sided quotes on a daily basis under NOM rules.¹⁴ Specifically, the Exchange represents that “any interest that is executable against a

NOM Participant’s quotes and orders that are received by the Exchange prior to the time the Kill Switch is processed by the System will automatically execute at the price up to the NOM Participant’s size.”¹⁵ In that respect, the Exchange further represented that “[t]he Kill Switch message will be accepted by the System in the order of receipt in the queue and will be processed in that order so that interest that is already accepted into the System will be processed prior to the Kill Switch message.”¹⁶ Based on these representations, the Commission believes that the proposal is designed to promote just and equitable principles of trade and perfect the mechanism of a free and open market.

Accordingly, the Commission finds that the Exchange’s proposal is consistent with the Act, including Section 6(b)(5) thereof, in that it is designed to promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,¹⁷ that the proposed rule change (SR-NASDAQ-2015-096) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-26327 Filed 10-15-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76063A; File No. SR-NYSEARCA-2015-81]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change Amending Several Rules To Address Certain Order Handling Obligations on the Part of Its Floor Brokers

October 9, 2015.

AGENCY: Securities and Exchange Commission.

ACTION: Notice; correction.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ 15 U.S.C. 78s(b)(2).

¹⁸ 17 CFR 200.30-3(a)(12).

⁴ See *id.*

⁵ Orders submitted by NOM Market Makers over Ouch to Trade Options (“OTTO”) interface will be treated as quotes for purposes of this rule. See Notice, *supra* note 3, at 51850.

⁶ NOM Participants will be able to utilize an interface to send a message to the Exchange to initiate the Kill Switch, or they may contact the Exchange directly. See Notice, *supra* note 3, at note 3.

⁷ Permissible groups could be formed only within a single broker-dealer. For example, a group could include, but would not be limited to, all market maker accounts or all order entry ports. See Notice, *supra* note 3, at 51850.

⁸ In approving this proposed rule change, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁹ 15 U.S.C. 78f.

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ See Notice, *supra* note 3, at 51851.

¹² See *id.*

¹³ See *id.*

¹⁴ See *id.*

SUMMARY: The Securities and Exchange Commission published a document in the **Federal Register** of October 9, 2015 concerning a Notice of Filing of Proposed Rule Change Amending Several Rules to Address Certain Order Handling Obligations on the Part of Its Floor Brokers. The document incorrectly indicated that the Commission had waived the operative delay for the proposed rule change.

FOR FURTHER INFORMATION CONTACT: Marc F. McKayle, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, (202) 551-5633.

Correction

In the **Federal Register** of October 7, 2015, in FR Doc No: 2015-25463, on page 60723, the sentences from the 24th line through the 42nd line of the third column referring to the operative delay should be deleted.

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-26330 Filed 10-15-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-76122; File No. SR-ICC-2015-015]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Related to the ICC Rule Enforcement Process for Missed Submissions

October 9, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on September 30, 2015, ICE Clear Credit LLC (“ICC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. 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 purpose of the proposed changes is to make revisions to the ICC Clearing Rules (the “Rules”) related to the ICC rule enforcement process for Missed Submissions.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC 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. ICC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of these statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

As part of ICC’s end-of-day price discovery process, ICC Clearing Participants (“CPs”) are required to submit end-of-day prices for specific instruments related to their open interest at ICC, in accordance with Rule 404(b) and ICC Procedures. Failure of a CP to provide submissions required by ICC pursuant to Rule 404(b) and ICC Procedures constitute a Missed Submission. In order to provide incentive against Missed Submissions, ICC has adopted a summary assessment approach described in Rule 702(e) and Schedule 702 of the Rules.

Currently, under Rule 702(e)(ii)(2), a CP may be eligible for a once-in-a-lifetime conditional waiver from such assessments, if one or more Missed Submissions are the first instance(s) of a Missed Submission for the type of instrument (index or single name) and the CP provides adequate explanation of the cause and plans for remedial actions.

Given the increased automation of price submissions, ICC recognizes that there may be circumstances, due to technological failures, which may result in Missed Submissions. Furthermore, due to the significant length of time since the inception of the end-of-day process, many CPs have utilized their once-in-a-lifetime waiver. As such, ICC believes it is reasonable to provide, under limited circumstances, a conditional once-a-year waiver for such Missed Submissions caused by technical failures, as described below. Such Rule changes will not affect the integrity and effectiveness of the end-of-day price discovery process. ICC believes such Rule changes provide a valuable and practical balance between the technicalities of the price discovery process and appropriate penalization for Missed Submissions.

The proposed Rule text provides for the replacement of ICC’s current once-in-a-lifetime waiver for Missed Submissions with a conditional once-a-year waiver for Missed Submissions caused by technical failures. Under revised Rule 702(e)(ii)(2), a CP would be eligible for one waiver per year for single name Missed Submissions, and one waiver per year for index Missed Submissions. A CP may request such waiver(s) be applied against all Missed Submissions for a given instrument class on a given day. A CP would be required to provide documentation with a waiver request, explaining that the root-cause of the Missed Submission was a technology issue and including a remediation plan to fix the cause of the Missed Submission. ICC would review and evaluate the waiver request and accept unless it had legitimate concerns that the root-cause of the Missed Submission had not been adequately identified, was not due to a technical issue, and/or would not be corrected by the provided remediation plan. ICC would maintain its current ability to provide waivers for Missed Submissions deemed to be due to extraordinary circumstances outside of a CP’s control, as set forth in Rule 702(e)(ii)(3). Pending regulatory approval, ICC plans to implement these changes on January 1, 2016, and apply the once-a-year waiver to the 2016 calendar year, and each calendar year going forward. There are no changes to ICC policies and procedures as a result of the Rule changes.

Section 17A(b)(3)(F) of the Act³ requires, among other things, that the rules of a clearing agency be designed to protect investors and the public interest and to comply with the provisions of the Act and the rules and regulations thereunder. ICC believes that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to ICC, in particular, to Section 17(A)(b)(3)(F),⁴ because ICC believes that the proposed rule changes will assure the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions, as the proposed revisions enhance ICC’s price discovery process, by ensuring a fair and equitable assessment structure. As such, the proposed changes are designed to promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78q-1(b)(3)(F).

⁴ *Id.*

within the meaning of Section 17A(b)(3)(F)⁵ of the Act.

Furthermore, such proposed changes are designed to ensure that CPs are appropriately disciplined for violations of ICC's rules, specifically Missed Submissions, through an appropriate fining structure, in accordance with Section 17A(b)(3)(G).⁶ Finally, such proposed rule changes are intended to provide a fair procedure with respect to the disciplining of CPs for Missed Submissions, in accordance with Section 17A(b)(3)(H).⁷

B. Self-Regulatory Organization's Statement on Burden on Competition

ICC does not believe the proposed rule changes would have any impact, or impose any burden, on competition. The Rule changes related to the ICC rule enforcement process for Missed Submissions apply uniformly across all market participants. Therefore, ICC does not believe the proposed rule changes impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove 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-ICC-2015-015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-ICC-2015-015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's Web site at <https://www.theice.com/clear-credit/regulation>.

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-ICC-2015-015 and should be submitted on or before November 6, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-26325 Filed 10-15-15; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 9318]

Culturally Significant Objects Imported for Exhibition Determinations: "Picturing the Americas: Landscape Painting From Tierra del Fuego to the Arctic" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Picturing the Americas: Landscape Painting from Tierra del Fuego to the Arctic," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Crystal Bridges Museum of American Art, Bentonville, Arkansas, from on about November 7, 2015, until on or about January 18, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202-632-6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/PD, SA-5, Suite 5H03, Washington, DC 20522-0505.

Dated: October 6, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015-26399 Filed 10-15-15; 8:45 am]

BILLING CODE 4710-05-P

⁵ *Id.*

⁶ 15 U.S.C. 78q-1(b)(3)(G).

⁷ 15 U.S.C. 78q-1(b)(3)(H).

⁸ 17 CFR 200.30-3(a)(12).

DEPARTMENT OF STATE**[Public Notice: 9319]****Culturally Significant Objects Imported for Exhibition Determinations: “Woven Gold: Tapestries of Louis XIV” Exhibition**

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition “Woven Gold: Tapestries of Louis XIV,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum, Los Angeles, California, from on or about December 15, 2015, until on or about May 1, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/DP, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: October 6, 2015.

Kelly Keiderling,*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2015–26401 Filed 10–15–15; 8:45 am]

BILLING CODE 4710–05–P**DEPARTMENT OF STATE****[Public Notice: 9317]****Culturally Significant Objects Imported for Exhibition Determinations: “The Greeks—Agamemnon to Alexander the Great” Exhibition**

SUMMARY: Notice is hereby given of the following determinations: Pursuant to

the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition “The Greeks—Agamemnon to Alexander the Great,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Field Museum of Natural History, Chicago, Illinois, from on or about November 25, 2015, until on or about April 10, 2016, at the National Geographic Museum, Washington, District of Columbia, from on or about May 26, 2016, until on or about October 9, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@state.gov). The mailing address is U.S. Department of State, L/DP, SA–5, Suite 5H03, Washington, DC 20522–0505.

Kelly Keiderling,*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2015–26382 Filed 10–15–15; 8:45 am]

BILLING CODE 4710–05–P**DEPARTMENT OF TRANSPORTATION****Maritime Administration****[Docket No. MARAD–2015–0118]****Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PAESANA; 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 November 16, 2015.

ADDRESSES: Comments should refer to docket number MARAD–2015–0118. 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 PAESANA is:

Intended Commercial Use of Vessel: “To charter inshore up to 12 passengers for hire for private charter, and port-to-port cruises.”

Geographic Region: Washington, DC, Florida, Maryland, Virginia, North Carolina, South Carolina, and Georgia

The complete application is given in DOT docket MARAD–2015–0118 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: October 6, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-26208 Filed 10-15-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number USCG-2013-0363]

Deepwater Port License Application: Liberty Natural Gas LLC, Port Ambrose Deepwater Port; Final Application Public Hearing and Final Environmental Impact Statement

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of availability; notice of public hearing; request for comments.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce: (1) The schedule and locations of public hearings; and (2) the availability of the Final Environmental Impact Statement (FEIS) for the Liberty Natural Gas LLC, Port Ambrose Liquefied Natural Gas Deepwater Port license application for the importation of natural gas.

The Port Ambrose application describes an offshore natural gas deepwater port facility that would be located 16.1 nautical miles southeast of Jones Beach, New York, 24.9 nautical miles east of Long Branch, New Jersey, and 27.1 nautical miles from the entrance to New York Harbor in a water depth of approximately 103 feet. The FEIS complies with the Deepwater Port Act of 1974, as amended (33 U.S.C. 1501 *et seq.*) (DWPA) and the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)), as implemented by the Council on Environmental Quality regulations (40 CFR 1500 to 1508).

MARAD and the USCG request public comments on the FEIS and the application.

Publication of this notice begins a 45-day comment period, requests public participation in the process, provides information on how to participate in the process and announces informational open houses and public hearings in New York and New Jersey. Pursuant to the criteria provided in the DWPA, both New Jersey and New York have been designated as Adjacent Coastal States (ACS) for this application.

Please note that this application is only for the construction and operation of a deepwater port that could only be used as a natural gas import facility. The considerable technical, operational and environmental differences between import and export operations for natural gas deepwater ports is such that any licensed deepwater port facility that proposed to convert from import to export operations would be required to submit a new license application (including application fee) and conform to all licensing requirements and regulations in effect at such time of application. In addition to payment of the application fee, licensing requirements include, but are not limited to, completion of an extensive environmental impact assessment which would include public participation and a financial responsibility review which would include public participation.

DATES: There will be a total of four public hearings held in connection with the application and the FEIS; two public hearings will be held in Long Beach, New York on November 2, 2015 and November 3, 2015, from 6:00 to 10:00 p.m.; and two public hearings will be held in Eatontown, New Jersey on November 4, 2015 and November 5, 2015, from 6:00 to 10:00 p.m. Each public hearing will be preceded by an open house from 4:30 to 5:30 p.m. The public hearing may end later than the stated time, depending on the number of persons wishing to speak. Additionally, materials submitted in response to the request for comments must reach the Docket Management Facility as detailed below, by close of business Monday, November 30, 2015, or 45 days after publication of this notice in the **Federal Register** whichever is later.

Federal and State agencies must also submit comments, recommended conditions for licensing, or letters of no objection by Monday, November 30, 2015, or 45 days after publication of this notice in the **Federal Register** whichever is later. Also, within 45 days following the final hearing, on or prior

to December 21, 2015, the Governor of New York and the Governor of New Jersey (ACS Governors) may approve, disapprove, or notify MARAD of inconsistencies with State programs relating to environmental protection, land and water use, and coastal zone management for which MARAD may ensure consistency by placing conditions on the license.

MARAD must issue a Record of Decision (ROD) to approve, approve with conditions, or deny the deepwater port license application, within 90 days following the final license hearing, on or prior to February 3, 2016.

ADDRESSES: The open houses and public hearings in Long Beach, New York will be held at the Long Beach Hotel, 405 East Broadway, Long Beach, New York, 11561; phone 516-544-4444. Free street parking is available, and the parking lot at the Long Island Railroad (LIRR) Long Beach Train Station, near Park Place and Park Avenue is available from 5:00 p.m. to 5:00 a.m. The City of Long Beach operates local bus public transportation services between the LIRR Long Beach Train Station and the Long Beach Hotel. The open houses and public hearings in Eatontown, New Jersey will be held at the Sheraton Eatontown Hotel, 6 Industrial Way East, Eatontown, NJ 07724; phone 732-542-6500. Free parking is available on site at the hotel.

The FEIS, license application, comments, supporting information and other associated documentation are available for viewing at the Federal Docket Management System (FDMS) Web site: <http://www.regulations.gov> under docket number USCG-2013-0363. The FEIS is also available at the following public libraries: Oceanside Library, 30 Davison Avenue, Oceanside, NY 11572; phone 516-766-2360; Long Beach Public Library, 111 W Park Ave, Long Beach, NY 11561; phone 516-432-7200; Long Branch Free Public Library, 328 Broadway, Long Branch, NJ 07740; phone 732-222-3900; and Queens Jamaica Library, 889-11 Merrick Blvd., Jamaica, NY 11432; phone 718-990-0700.

Docket submissions for USCG-2013-0363 should be addressed to: Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

The Federal Docket Management Facility accepts hand-delivered submissions and makes docket contents available for public inspection and copying at this address between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Facility telephone number is 202-366-

9329, fax number is 202-493-2251, and the Web site for electronic submissions to the FDMS or for electronic access to docket contents is <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Roddy Bachman, U.S. Coast Guard, telephone 202-372-1451, email: Roddy.C.Bachman@uscg.mil, or Ms. Yvette M. Fields, Maritime Administration, telephone 202-366-0926, email: Yvette.Fields@dot.gov. For questions regarding the Docket, please call Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Hearing and Open House

You are invited to learn about the proposed Port Ambrose Deepwater Port at one of the above noticed informational open houses, and to comment on the application and the environmental impact analysis contained in the FEIS at any of the above public hearings or directly to the docket. The open houses, public hearings and docket comments will be used by MARAD to inform the Maritime Administrator's decision making process, including the ROD and any conditions that may be placed on a subsequent license to own, construct and operate a deepwater port.

Speakers may register upon arrival (registration by proxy is not authorized) and will be recognized in the following order: Elected officials, public agencies, individuals or groups in the order in which they registered. In order to accommodate all speakers, speaker time may be limited, hearing hours may be extended, or both. Speakers' transcribed remarks will be included in the public docket. Written material may also be submitted for inclusion in the public docket. Written material must include the author's name. We request attendees respect the hearing procedures in order to ensure a constructive hearing. Please do not bring signs or banners inside the hearing venue. The presiding officer will use his/her discretion to conduct the hearing in an orderly manner. In the interest of allowing all interested parties to speak, and because all comments that are received, both verbal and written, are included in the record and will be considered by MARAD before making a licensing decision, it is not necessary to sign up more than once to provide duplicate comments at subsequent meetings.

Public hearing locations are wheelchair-accessible. However, attendees who require special assistance such as sign language interpretation or other reasonable accommodation, please

notify the USCG at least five business days in advance. See **FOR FURTHER INFORMATION CONTACT**. Include contact information as well as information about specific needs.

Request for Comments

We request public comments on the FEIS and the application. The public hearing is not the only opportunity you have to comment. In addition to, or in place of, attending a hearing, you may submit comments to the Federal Docket Management Facility during the public comment period. See **DATES**. We will consider all comments and material received during the comment period.

Submissions should include:

- Docket number USCG-2013-0363.
- Your name and address.

Submit comments or material using only one of the following methods:

- Electronic submission (preferred to expedite processing) to the FDMS, <http://www.regulations.gov>.

- Fax, mail, or hand delivery to the Federal Docket Management Facility. See **ADDRESSES**. Faxed or hand delivered submissions must be unbound, no larger than 8½ by 11 inches, and suitable for copying and electronic scanning. If you mail your submission and want to confirm it reaches the Facility, include a stamped, self-addressed postcard or envelope.

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the FDMS Web site (<http://www.regulations.gov>) and will include any personal information you provide. Therefore, submitting this information makes it a public record. See Privacy Act. You may view docket submissions at the Department of Transportation Docket Management Facility or electronically on the FDMS Web site. See **ADDRESSES**.

Background

Information about deepwater ports, DWPA, other applicable statutes, regulations governing deepwater port licensing, including the application review process and the receipt of the current application for the proposed Port Ambrose liquefied natural gas (LNG) deepwater port was published in the **Federal Register** on June 14, 2013, 78 FR 36014. The "Summary of the Application" from that publication is reprinted below for your convenience. The Notice of Intent to Prepare an environmental impact statement (EIS) for the proposed action was published in the **Federal Register** on June 24, 2013, (78 FR 37878), and the Notice of Availability of the Draft EIS was published in the **Federal Register** on

December 16, 2014, (79 FR 74808). The FEIS, application materials and associated comments and supporting information are available on the docket.

Proposed Action and Alternatives

USCG and MARAD are co-lead Federal agencies for the preparation of the FEIS; MARAD is the Federal licensing agency (action agency). The proposed action requiring environmental review is the Federal licensing of the proposed deepwater port described in the "Summary of the Application" below. The alternatives to licensing the proposed port are: (1) Licensing with conditions (including conditions designed to mitigate environmental impact) and (2) denying the application, which, for purposes of environmental review, is the "no-action" alternative. These alternatives are more fully discussed in the FEIS. You can address any questions about the proposed action or the FEIS to USCG or MARAD project managers identified in **FOR FURTHER INFORMATION CONTACT**.

Summary of the Application

Liberty Natural Gas, LLC is proposing to construct, own and operate a LNG deepwater port import facility, known as Port Ambrose, located in the New York Bight. The Port Ambrose facility will be located at a different proposed location and include a different design than the previous deepwater port license application submitted by Liberty Natural Gas, LLC in 2010. Port Ambrose would consist of two Submerged Turret Loading Buoys (STL Buoys) in Federal waters 16.1 nautical miles southeast of Jones Beach, New York, 24.9 nautical miles east of Long Branch, New Jersey and 27.1 nautical miles from the entrance to New York Harbor, in a water depth of approximately 103 feet.

LNG would be delivered from purpose-built LNG regasification vessels (LNGRVs), vaporized on site and delivered through the STL Buoys, flexible riser/umbilical, subsea manifold and lateral pipelines to a buried 18.8 nautical mile subsea mainline connecting to the existing Transco Lower New York Bay Lateral in New York State waters 2.2 nautical miles southwest of Long Beach, New York and 13.1 nautical miles east of Sandy Hook, New Jersey. The STL Buoys would be lowered to rest on a landing pad when not in use and would also include a suction anchor mooring array.

STL Buoy 1 is located at Latitude: 40°19'24.61" N and Longitude: 73°25'45.33" W. STL Buoy 2 is located at Latitude: 40°20'09.26" N and Longitude 73°23'51.92" W. The Port

components would fall in the following U.S. Outer Continental Shelf (OCS) lease blocks:

Buoy 1 (6708, 6709, 6758); Buoy 2 (6709); Lateral 1 (6708); Lateral 2 (6708, 6709); "Y" Assembly (6708); Mainline Pipeline (6708, 6658, 6657, 6607, 6606, 6556, 6555, 6554, 6504 and 6503).

The 145,000 cubic meter LNGRVs would have onboard closed-loop vaporization and metering and odorant capability. Each vessel would have three vaporization units capable of maximum send-out of 750 million standard cubic feet per day (MMscfd) (maximum pipeline system flow rate is 660 MMscfd with two buoys) with annual average expected to be 400 MMscfd. The LNGRVs have been designed to use a ballast water cooling system that will entirely re-circulate onboard the vessel during Port operations, eliminating vessel discharges associated with regasification while at the Port. Deliveries through Port Ambrose would be focused during peak demand winter and summer months, and it is anticipated that approximately 45 deliveries will occur each year.

As proposed, the LNGRVs would access the port inbound from the Hudson Canyon to Ambrose Traffic Lane and depart via the Ambrose to Nantucket Traffic Lane. MARAD and USCG are aware that Port Ambrose falls within the proposed area of interest for the Long Island—New York City Offshore Wind Collaborative wind energy project. This project has been acknowledged and considered in the cumulative impacts analysis section of the FEIS based on currently available information. If approved, the majority of the port and pipeline construction and installation would occur in 2017, with commissioning estimated to be in December 2018.

In addition, pipelines and structures such as the STL Buoy moorings will require permits under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act, which are administered by the U.S. Army Corps of Engineers (USACE). Port Ambrose will also require permits from the Environmental Protection Agency (EPA) pursuant to the provisions of the Clean Air Act, as amended, and the Clean Water Act, as amended.

The new pipeline is included in the NEPA review as part of the deepwater port application process. The EPA and the USACE, among others, are cooperating agencies (40 CFR 1501.6) and have assisted in development of the FEIS. See 40 CFR 1501.6. To the extent required, each agency will incorporate the FEIS into their permitting processes. Comments sent to the EPA or USACE

will be incorporated in the USCG Port Ambrose docket and considered under this notice to ensure consistency with the NEPA Process.

There have been some proposed project changes since the original Port Ambrose application was submitted, which were set forth in the Notice of Availability of the Draft EIS (DEIS). In summary, these include: (1) The original Application proposed a plowed mainline pipeline burial depth of three (3) feet to top of pipe. Pursuant to USACE requirements, the mainline pipeline is now proposed to be plow-buried to seven (7) feet (4 feet to top of pipe), and for approximately three (3) miles within the Ambrose Anchorage Area, buried to 10 feet (7 feet to top of pipe). The pipeline within the Ambrose Anchorage Area will then be backfilled and covered with three (3) feet of 8-inch rock to a point. Once the rock has been placed, gravelly sand will be deposited on top of the rock covered pipeline to restore the seabed to near its original seafloor bottom elevation; (2) the originally proposed impact driven mooring pile anchors are now proposed to be suction anchors; (3) the original port construction and commissioning was proposed to occur in 2015. This timetable has been amended to occur in 2018 (assuming license is approved and issued). Should a license be issued, the deepwater port would be designed, fabricated, constructed, commissioned, maintained, inspected and operated in accordance with applicable codes and standards.

Privacy Act

The electronic form of all comments received into the FDMS can be searched by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). The DOT Privacy Act Statement can be viewed in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Authority: The Deepwater Port Act of 1974, as amended, 33 U.S.C. 1501 *et seq.*; 49 CFR 1.93.

* * * * *

Dated: October 5, 2015.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015-25727 Filed 10-15-15; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 57 (Sub-No. 63X)]

Soo Line Railroad Company— Abandonment Exemption—in Cook County, Ill.

Soo Line Railroad Company d/b/a Canadian Pacific (Soo Line) has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon approximately 5,253 feet of railroad line between milepost 0.0 +/- (milepost 8.9 +/- on the Metra main line) and milepost 0.9 +/- at the intersection of Diversey Avenue in Chicago (Dunning Line), in Cook County, Ill. (the Line). The Line traverses United States Postal Service Zip Code 60707.

Soo Line has certified that: (1) No local traffic has moved over the Line for at least two years; (2) any overhead traffic can be and has been rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on November 17, 2015, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,¹ formal expressions of intent to

¹ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C. 2d 377 (1989). Any request for a stay should

file an OFA under 49 CFR 1152.27(c)(2),² and trail use/rail banking requests under 49 CFR 1152.29 must be filed by October 26, 2015. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by November 5, 2015, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423-0001.

A copy of any petition filed with the Board should be sent to Soo Line's representative: W. Karl Hansen, Stinson Leonard Street LLP, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Soo Line has filed environmental and historic reports that address the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by October 23, 2015. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423-0001) or by calling OEA at (202) 245-0305. Assistance for the hearing impaired is available through the Federal Information Relay Service at (800) 877-8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), Soo Line shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by Soo Line's filing of a notice of consummation by October 16, 2016, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

² Each OFA must be accompanied by the filing fee, which is currently set at \$1,600. See 49 CFR 1002.2(f)(25).

Board decisions and notices are available on our Web site at "www.stb.dot.gov."

Decided: October 13, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2015-26383 Filed 10-15-15; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. FD 35874]

Lone Star Railroad, Inc. and Southern Switching Company—Track Construction and Operation Exemption—in Howard County, Tex

AGENCY: Surface Transportation Board.

ACTION: Issuance of Draft Environmental Assessment; Request for Comments.

SUMMARY: On February 24, 2015, Applicants, Lone Star Railroad, Inc. (LSR) and Southern Switching Company (SSC), filed a petition with the Surface Transportation Board (Board) pursuant to 49 United States Code (U.S.C.) 10502 and 49 Code of Federal Regulations (CFR) 1121.1. The Board's Office of Environmental Analysis (OEA) is responsible for ensuring the Board's compliance with the requirements of the National Environmental Policy Act. Applicants seek Board authority for LSR to construct and SSC to operate approximately 3.18 miles of rail line that would connect to an existing Union Pacific Railroad Company mainline and provide rail service to an industrial park property near Big Spring, in Howard County, Texas. The primary purpose for the proposed action is the efficient delivery of frac sand by rail to the industrial park property, where it would be transloaded to trucks for delivery to crude oil wellhead locations in the Permian Basin. Applicants anticipate that the proposed rail line would support an average of five trains per week.

Today, OEA has issued the Draft Environmental Assessment (EA), which

is available on the Board's Web site, www.stb.dot.gov, by clicking "Decisions" under "Quick Links," and locating the document under the service date of 10/16/2015. The Draft EA identifies the natural and man-made resources in the area of the proposed rail line and analyzes the potential impacts of the proposal on these resources. Based on the information provided from all sources to date and its independent analysis, OEA preliminarily concludes that construction of the proposed rail line would have no significant environmental impacts if the Board imposes and Applicants implement the recommended mitigation measures set forth in the Draft EA.

DATES: Interested parties are invited to submit written comments on the Draft EA by November 16, 2015. OEA will consider and respond to comments received on the Draft EA in the Final EA. The Board will issue a final decision on the proposed transaction after issuance of the Final EA.

Filing Environmental Comments: Comments submitted by mail should be addressed to: Kenneth Blodgett, Surface Transportation Board, 395 E Street SW., Washington, DC 20423-0001, Attention: Environmental Filing, Docket No. FD 35874. Comments may also be submitted electronically on the Board's Web site, www.stb.dot.gov, by clicking on the "E-FILING" link on the home page and then selecting "Environmental Comments." Please refer to *Docket No. FD 35874* in all correspondence, including e-filings, addressed to the Board.

FOR FURTHER INFORMATION CONTACT: Kenneth Blodgett at the address above or by phone at 202-245-0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339.

By the Board, Victoria Rutson, Director, Office of Environmental Analysis.

Tia Delano,

Clearance Clerk.

[FR Doc. 2015-26313 Filed 10-15-15; 8:45 am]

BILLING CODE 4915-01-P



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Part II

Department of Health and Human Services

Office of the Secretary

45 CFR Part 170

2015 Edition Health Information Technology (Health IT) Certification
Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and
ONC Health IT Certification Program Modifications; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB93

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule finalizes a new edition of certification criteria (the 2015 Edition health IT certification criteria or “2015 Edition”) and a new 2015 Edition Base Electronic Health Record (EHR) definition, while also modifying the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings. The 2015 Edition establishes the capabilities and specifies the related standards and implementation specifications that Certified Electronic Health Record Technology (CEHRT) would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) when such edition is required for use under these programs.

DATES: These regulations are effective January 14, 2016, except for § 170.523(m) and (n), which are effective on April 1, 2016.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of January 14, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION:

Commonly Used Acronyms

API Application Programming Interface
 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 IT Product List
 CLIA Clinical Laboratory Improvement Amendments
 CMS Centers for Medicare & Medicaid Services
 CQM Clinical Quality Measure
 EHR Electronic Health Record
 FDA Food and Drug Administration
 HHS Department of Health and Human Services
 HISP Health Information Service Providers
 HIT Health Information Technology
 HITPC HIT Policy Committee
 HITSC HIT Standards Committee
 HL7 Health Level Seven
 IG Implementation Guide
 LOINC® Logical Observation Identifiers Names and Codes
 NIST National Institute of Standards and Technology
 ONC Office of the National Coordinator for Health Information Technology
 SDO Standards Developing Organization
 SNOMED CT® Systematized Nomenclature of Medicine Clinical Terms

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I. Executive Summary

A. Purpose of Regulatory Action

Building on past rulemakings, we issued a proposed rule (“Proposed Rule”) (80 FR 16804) that identified how health IT certification to the proposed 2015 Edition health IT certification criteria could support the establishment of an interoperable nationwide health information infrastructure. The Proposed Rule reflected stakeholder feedback received through various outreach initiatives, including the regulatory process, and was designed to broadly support the health care continuum through the use of certified health IT. This final rule, taking into account public comments received on the Proposed Rule, continues to focus on the establishment of an interoperable nationwide health information infrastructure, through the same means identified in the Proposed Rule and recited below, but with an additional focus on reducing health IT developer and provider burden as compared to the Proposed Rule. To this end, this final rule will:

- Improve interoperability for specific purposes by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information, including a Common Clinical Data Set composed primarily of data expressed using adopted standards; and rigorously testing an identified content exchange

standard (Consolidated Clinical Document Architecture (C-CDA));

- Facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface (API) capabilities in the 2015 Edition Base Electronic Health Record (EHR) definition;

- Establish a framework that makes the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program open and accessible to more types of health IT, health IT that supports a variety of care and practice settings, various HHS programs, and public and private interests;

- Support the Centers for Medicare & Medicaid Services (CMS) Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) through the adoption of a set of certification criteria that align with proposals for Stage 3;

- Address health disparities by providing certification: to standards for more granular capture of race and ethnicity; the collection of sexual orientation, gender identity, social, psychological, and behavioral data; for the exchange of sensitive health information (Data Segmentation for Privacy); and for the accessibility of health IT;

- Ensure all health IT presented for certification possess the relevant privacy and security capabilities;

- Improve patient safety by: applying enhanced user-centered design principles to health IT, enhancing patient matching, requiring health IT to be capable of exchanging relevant patient information (e.g., Unique Device Identifiers), improving the surveillance of certified health IT, and making more information about certified products publicly available and accessible;

- Increase the reliability and transparency of certified health IT through surveillance and disclosure requirements; and

- Provide health IT developers with more flexibility, opportunities, and *time* for development and certification of health IT that supports interoperability, usability, and innovation.

B. Summary of Major Provisions

1. Overview of the 2015 Edition Health IT Certification Criteria

The 2015 Edition health IT certification criteria (“2015 Edition” or “2015 Edition certification criteria”) facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria,

standards, and implementation specifications. It incorporates changes that are designed to spur innovation, open new market opportunities, and provide more choices to providers when it comes to electronic health information exchange. To achieve these goals, new “application access” (also known as “API”) certification criteria have been adopted that will require the demonstration of an API that responds to data requests for any one category of the data referenced in the Common Clinical Data Set as well as for all of the data referenced in the Common Clinical Data Set. We note that in response to comments, we have separated this criterion into 3 criteria to provide health IT developers and providers more flexibility. To further validate the continued interoperability of certified health IT and the ability to exchange electronic health information with health IT certified to the 2014 Edition, 2015 Edition, and potentially future editions, a new “transitions of care” certification criterion will rigorously assess a product’s ability to create and receive an interoperable C-CDA. We have also adopted certification criteria that both support interoperability and other settings and use cases, such as the “Common Clinical Data Set summary record,” “data segmentation for privacy,” and “care plan” certification criteria.

We refer readers to section III.A for an overview table (Table 2) of certification criteria adopted in this final rule as compared to the certification criteria proposed in the Proposed Rule and the adopted 2014 Edition. We also refer readers to sections III.A.3 and III.A.5 of this preamble for full discussions of certification criteria adopted as part of the 2015 Edition in this final rule (III.A.3) and the proposed certification criteria not adopted in this final rule (III.A.5).

2. Health IT Definitions

a. Base EHR Definitions

This final rule adopts a Base EHR definition specific to the 2015 Edition (i.e., a 2015 Edition Base EHR definition) at § 170.102 and renames the current Base EHR definition at § 170.102 as the 2014 Edition Base EHR definition. The 2015 Edition Base EHR definition differs from the 2014 Edition Base EHR definition in the following ways:

- It does not include privacy and security capabilities and certification criteria.

- It only includes capabilities to record and export clinical quality measure (CQM) data (§ 170.315(c)(1))

and not other CQM capabilities such as import, calculate, and “report to CMS.”

- It includes the 2015 Edition “smoking status” certification criterion as patient demographic and clinical health information data consistent with statutory requirements.¹

- It includes the 2015 Edition “implantable device list” certification criterion as patient demographic and clinical health information data consistent with statutory requirements.²

- It includes the 2015 Edition “API” certification criteria as capabilities that support both the capture and query of information relevant to health care quality and exchange electronic health information with, and integrate such information from other sources.³

- It includes the proposed 2015 Edition certification criteria that correspond to the remaining 2014 Edition certification criteria referenced in the “2014 Edition” Base EHR definition (i.e., CPOE, demographics, problem list, medication list, medication allergy list, CDS, transitions of care, data portability, and relevant transport certification criteria). For the transport certification criteria, we include the “Direct Project” criterion (§ 170.315(h)(1)) as well as the “Direct Project, Edge Protocol and XDR/XDM” criterion (§ 170.315(h)(2)) as equivalent alternative means for meeting the 2015 Edition Base EHR definition.

We refer readers to section III.B.1 of this preamble for a more detailed discussion of the 2015 Edition Base EHR definition and to section III.A.3 of this preamble for a full discussion of the criteria that have been included in the Base EHR definition. Of note, the “demographics” certification criterion (§ 170.315(a)(5)) now includes sexual orientation and gender identity as data elements, the “smoking status” certification criterion (§ 170.315(a)(11)) is now only a functional requirement, the “API” criterion has been separated into 3 distinct criteria as mentioned above, and the Direct-related criteria have been updated from “unchanged” to “revised” to incorporate updated and necessary interoperability standards.

As discussed in more detail under the “privacy and security” heading in section IV.C.1 of this preamble, Health

¹ A Base EHR is the regulatory term we have given to what the HITECH Act defines as a “qualified EHR.” Our Base EHR definition(s) include all capabilities found in the “qualified EHR.” Please see the 2014 Edition final rule (77 FR 54262) for further explanation.

² A capability included in the Base EHR definition, which originates from the “qualified EHR” definition found in the HITECH Act.

³ These are capabilities included in the Base EHR definition, which originate from the “qualified EHR” definition found in the HITECH Act.

IT Modules presented for certification to criteria listed in the 2015 Base EHR definition and other 2015 Edition certification criteria *will be* subject to the applicable privacy and security criteria for the purposes of certification.

The CQM capabilities noted above as not included in the 2015 Edition Base EHR definition have, however, been included in the Certified EHR Technology (CEHRT) definition under the EHR Incentive Programs. We refer readers to the next section (“b. CEHRT definition”) for further information and guidance on the relationship of the 2015 Edition Base EHR definition and the 2015 Edition certification criteria with the CEHRT definition. We also refer readers to the CEHRT definition finalized in the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register** as the authoritative source for the requirements to meet the CEHRT definition.

b. CEHRT Definition

This final rule removes the CEHRT definition from § 170.102 for the following reasons. The CEHRT definition has always been defined in a manner that supports the EHR Incentive Programs. As such, the CEHRT definition more appropriately resides solely within the EHR Incentive Programs regulations. This is also consistent with our approach in this final rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. Further, this adds administrative simplicity in that regulatory provisions, which EHR Incentive Programs participants must meet (*e.g.*, the CEHRT definition), are defined within the context of rulemakings for those programs.

We note that the CEHRT definition finalized by CMS continues to include the Base EHR definition(s) defined by ONC, including the 2015 Edition Base EHR definition adopted in this final rule. We also refer readers to Table 4 (“2015 Edition Health IT Certification Criteria Associated with the EHR Incentive Programs Stage 3”) found in section III.A.3 of this preamble. Table 4 crosswalks 2015 Edition certification criteria with the finalized CEHRT definition and EHR Incentive Programs Stage 3 objectives. It also identifies mandatory and conditional certification requirements (*i.e.*, the application of certain certification criteria to Health IT Modules) that Health IT Modules presented for certification must meet

regardless of the setting or program the Health IT Module is designed to support.

For the full requirements to meet the CEHRT definition under the EHR Incentive Programs, including for years before 2018 and for 2018 and subsequent years, we refer readers to the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

c. Common Clinical Data Set

We revised the “Common MU Data Set” definition in § 170.102. We changed the name to “Common Clinical Data Set,” which aligns with our approach throughout this final rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. We also changed references to the “Common MU Data Set” in the 2014 Edition (§ 170.314) to “Common Clinical Data Set.”

We revised the definition to account for the new and updated standards and code sets we have adopted in this final rule for the 2015 Edition that will improve and advance interoperability through the exchange of the Common Clinical Data Set. We also revised the definition to support patient safety and improve care through clearly referenced data elements (“care plan data”) and the inclusion of new patient data (*e.g.*, Unique Device Identifiers (UDIs) and immunizations (with standards)). These revisions will *not* change the standards, codes sets, and data requirements specified in the Common Clinical Data Set for 2014 Edition certification, which remain unchanged. They only apply to health IT certified to the 2015 Edition certification criteria that reference the Common Clinical Data Set.

We refer readers to section III.B.3 of this preamble for a detailed discussion of the Common Clinical Data Set and a table listing the data and standards included in the Common Clinical Data Set for both the 2014 and 2015 Editions.

3. The ONC Health IT Certification Program and Health IT Module

We have changed the name of the ONC HIT Certification Program to the “ONC Health IT Certification Program.” We have also modified the ONC Health IT Certification Program in ways that will make it more accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient

settings. These modifications will also serve to support other public and private programs that may reference the use of health IT certified under the ONC Health IT Certification Program. When we established the certification program (76 FR 1262),⁴ we stated our initial focus would be on EHR technology and supporting the EHR Incentive Programs, which at the time, focused on the ambulatory setting and inpatient setting (76 FR 1294).

This final rule permits other types of health IT, such as technology implemented by health information service providers (HISPs) and health information exchanges (HIEs), to receive appropriate attribution and not be referenced by a certificate with “EHR” included in it. This final rule also supports health IT certification for other care and practice settings, such as long-term post-acute care (LTPAC), behavioral health, and pediatrics. Further, this final rule will make it simpler for certification criteria and certified health IT to be referenced by other HHS programs (*e.g.*, Medicare and Medicaid payment programs and various grant programs), other public programs, and private entities and associations.

a. Program Alignment Changes

As part of our approach to evolve the ONC Health IT Certification Program, we have replaced prior rulemaking use of “EHR” and “EHR technology” with “health IT.” The term health IT is reflective of the scope of ONC’s authority under the Public Health Service Act (§ 3000(5) as “health information technology” is so defined), and represents a broad range of technology, including EHR technology. It also more properly represents some of the technology, as noted above, that has been previously certified to editions of certification criteria under the ONC Health IT Certification Program and may be certified to the 2015 Edition. Similarly, to make the ONC Health IT Certification Program more open and accessible, we have renamed the EHR Module as “Health IT Module.”

b. “Meaningful Use Measurement”

We have adopted our proposed approach in that we will not require ONC-Authorized Certification Bodies (ONC-ACBs) to certify Health IT Modules to the 2015 Edition “meaningful use measurement” certification criteria. We note, however, that *CMS has included* the 2015 Edition

⁴ Please see section II.B.3 of this preamble for a regulatory history of the ONC Health IT Certification Program, including changes to the program’s name.

“meaningful use measurement” certification criteria in the CEHRT definition as a program requirement for the EHR Incentive Programs.

Accordingly, we encourage health IT developers supporting providers participating in the EHR Incentive Programs or providers’ quality improvement needs to seek certification to these criteria as appropriate for their Health IT Modules (e.g., a Health IT Module is presented for certification to a criterion that supports a Stage 3 objective with a percentage-based measure and the Health IT Module can meet the “automated numerator recording” criterion or “automated measure calculation” criterion).

c. Privacy and Security Certification Framework

We have adopted a new, simpler, straight-forward approach to privacy and security certification requirements for Health IT Modules certified to the 2015 Edition. In sum, the privacy and security certification criteria applicable to a Health IT Module presented for certification is based on the other capabilities included in the Health IT Module and for which certification is sought. Under the 2015 Edition privacy and security certification framework, a health IT developer will know exactly what it needs to do in order to get its Health IT Module certified and a purchaser of a Health IT Module will

know exactly what privacy and security functionality against which the Health IT Module had to be tested in order to be certified.

d. Principles of Proper Conduct (PoPC) for ONC-ACBs

We have adopted new and revised PoPC for ONC-ACBs. ONC-ACBs are now required to report an expanded set of information to ONC for inclusion in the open data file that would make up the Certified Health IT Product List (CHPL). ONC-ACBs must ensure that health IT developers provide more meaningful disclosure of certain types of costs and limitations that could interfere with the ability of users to implement certified health IT in a manner consistent with its certification. ONC-ACBs must retain records for a period of time that will support HHS program needs. ONC-ACBs must also obtain a record of all adaptations and updates affecting “safety-enhanced design” criteria on a quarterly basis each calendar year. ONC-ACBs must also report to the National Coordinator complaints received on certified health IT. We have also adopted new requirements for “in-the-field” surveillance under the ONC Health IT Certification Program that clarify and expand ONC-ACBs’ existing surveillance responsibilities by specifying requirements and procedures for in-the-field surveillance. We believe

these new and revised PoPC promote greater transparency and accountability for the ONC Health IT Certification Program.

C. Costs and Benefits

Our estimates indicate that this final rule is an economically significant rule as its overall costs for health IT developers may be greater than \$100 million in at least one year. We have, therefore, projected the costs and benefits of the final rule. The estimated costs expected to be incurred by health IT developers to develop and prepare health IT to be tested and certified in accordance with the 2015 Edition certification criteria (and the standards and implementation specifications they include) are represented in monetary terms in Table 1 below. We note that this final rule does not impose the costs cited as compliance costs, but rather as investments which health IT developers voluntarily take on and may expect to recover with an appropriate rate of return. We further note that, based on the estimates provided by a health IT developer association in response to the Proposed Rule, we have reduced the estimated burden of the 2015 Edition by over 40,000 burden hours per health IT developer by not adopting certain proposed certification criteria, functionality and standards.

The dollar amounts expressed in Table 1 are expressed in 2014 dollars.

TABLE 1—DISTRIBUTED TOTAL 2015 EDITION DEVELOPMENT AND PREPARATION COSTS FOR HEALTH IT DEVELOPERS (4-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (%)	Total low cost estimate (\$M)	Total high cost estimate (\$M)	Total average cost estimate (\$M)
2015	15	39.07	60.48	49.77
2016	35	91.15	141.12	116.14
2017	35	91.15	141.12	116.14
2018	15	39.07	60.48	49.77
4-Year Totals	260.44	403.19	331.82

As noted above, we expect that health IT developers will recover an appropriate rate of return for their investments in developing and preparing their health IT for certification to the 2015 Edition certification criteria adopted in this final rule. However, we do not have data available to quantify these benefits or other benefits that will likely arise from health IT developers certifying their health IT to the 2015 Edition.

We believe that there will be several significant benefits that may arise from this final rule for patients, health care providers, and health IT developers.

The 2015 Edition continues to improve health IT interoperability through the adoption of new and updated standards and implementation specifications. For example, many proposed certification criteria include standards and implementation specifications for interoperability that directly support the EHR Incentive Programs, which include objectives and measures for the interoperable exchange of health information and for providing patients electronic access to their health information in structured formats. In addition, the adopted certification criteria that support the collection of

patient data that could be used to address health disparities would not only benefit patients, but the entire health care delivery system through improved quality of care. The 2015 Edition also supports usability and patient safety through new and enhanced certification requirements for health IT.

This final rule also makes the ONC Health IT Certification Program open and accessible to more types of health IT and for health IT that supports a variety of care and practice settings. This should benefit health IT developers, providers practicing in

other care/practice settings, and consumers through the availability and use of certified health IT that includes capabilities that promote interoperability and enhanced functionality.

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 Health IT Policy Committee (HITPC) and the Health IT 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 health IT standards, implementation specifications, and certification criteria.

2. Health IT 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 health IT. Specifically, section 3001(c)(5)(A) specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), 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 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 the 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 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 the EHR Incentive Programs 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 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 EHR Incentive Programs Stage 1 by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule (75 FR 44314) (the “EHR Incentive Programs Stage 1 final rule”).

The Secretary issued a proposed rule 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 proposed rule”), which proposed new and revised standards, implementation specifications, and certification criteria. After consideration of the comments received on the 2014 Edition proposed rule, 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

the EHR Incentive Programs Stage 2, as well as 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”). 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 the EHR Incentive Programs Stage 2 by EPs, eligible hospitals, and CAHs under the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 final rule (77 FR 53968) (the “EHR Incentive Programs Stage 2 final rule”).

On December 7, 2012, an interim final rule with a request for comment was jointly issued and published by ONC and CMS to update certain standards that had been previously adopted in the 2014 Edition final rule. The interim final rule also revised the EHR Incentive Programs by adding an alternative measure for the Stage 2 objective for hospitals to provide structured electronic laboratory results to ambulatory providers, corrected the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission, and made the case number threshold exemption policy for clinical quality measure (CQM) reporting applicable for eligible hospitals and CAHs beginning with FY 2013. In addition, the interim final rule provided notice of CMS's intent to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012 (77 FR 72985). On September 4, 2014, a final rule (Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule) (79 FR 52910) was published adopting these proposals.

On November 4, 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.

On February 26, 2014, the Secretary published a proposed rule titled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements” (79 FR 10880) (“Voluntary Edition proposed rule”). The proposed rule proposed a voluntary edition of certification criteria that was designed to enhance interoperability, promote innovation, and incorporate “bug fixes” to improve upon the 2014 Edition. A correction notice was published for the Voluntary Edition proposed rule on March 19, 2014, entitled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Correction” (79 FR 15282). This correction notice corrected the preamble text and gap certification table for four certification criteria that were omitted from the list of certification criteria eligible for gap certification for the 2015 Edition EHR certification criteria. On September 11, 2014, a final rule was published titled “2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” (79 FR 54430) (“2014 Edition Release 2 final rule”). The final rule adopted a small subset of the original proposals in the Voluntary Edition proposed rule as optional and revised 2014 Edition EHR certification criteria that provide flexibility, clarity, and enhance health information exchange. It also finalized administrative proposals (i.e., removal of regulatory text from the Code of Federal Regulations (CFR)) and proposals for the ONC HIT Certification Program that provide improvements.

On May 23, 2014, CMS and ONC jointly published the “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition” proposed rule (79 FR 29732). The rule proposed to update the EHR Incentive Programs Stage 2 and Stage 3 participation timeline. It proposed to revise the CEHRT definition to permit the use of EHR technology certified to the 2011 Edition to meet the CEHRT definition for FY/CY 2014. It also proposed to allow EPs, eligible hospitals, and CAHs that could not fully implement EHR

technology certified to the 2014 Edition for an EHR reporting period in 2014 due to delays in the availability of such technology to continue to use EHR technology certified to the 2011 Edition or a combination of EHR technology certified to the 2011 Edition and 2014 Edition for the EHR reporting periods in CY 2014 and FY 2014. On September 4, 2014, a final rule (“CEHRT Flexibility final rule”) was published (79 FR 52910) adopting these proposals.

On March 30, 2015, the Secretary published a proposed rule titled “2015 Edition Health Information Technology (Health IT) Certification Criteria; 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 16804) (“2015 Edition Proposed Rule” or “Proposed Rule”). The Proposed Rule proposed an edition of certification criteria that was designed to enhance interoperability and is the subject of this final rule.

2. Medicare and Medicaid EHR Incentive Programs Rules

On January 13, 2010, CMS published the Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule (75 FR 1844). The rule proposed the criteria for Stage 1 of the EHR Incentive Programs 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 Stage 1 of 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, eligible hospitals, and CAHs must satisfy to meet Stage 1.

On March 7, 2012, CMS published the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; Proposed Rule (77 FR 13698). Subsequently, CMS published a final rule (77 FR 53968) for the EHR Incentive Programs on September 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, eligible hospitals, and CAHs must satisfy to meet Stage 2. It also revised some Stage 1 requirements.

As described above in Section II.B.1, ONC and CMS jointly issued an interim final rule with a request for comment that was published on December 7, 2012 and a final rule that was published on

September 4, 2014. Also, as described above in Section II.B.1, ONC and CMS jointly issued proposed and final rules that were published on May 23, 2014 and September 4, 2014, respectively.

On March 30, 2015, CMS published the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3; Proposed Rule (80 FR 16732) (“EHR Incentive Programs Stage 3 proposed rule”) outlining objectives, associated measures, and other requirements that EPs, eligible hospitals, and CAHs would need to meet to participate in Stage 3 of the EHR Incentive Programs.

On April 15, 2015, CMS published the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017; Proposed Rule (80 FR 20346) (“EHR Incentive Programs Modifications proposed rule”) proposing modifications to the EHR Incentive Programs for the EHR reporting periods and meaningful use measures in 2015 through 2017.

3. ONC Health IT 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) (“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-ACBs need to follow for certifying EHR Modules in a manner that provides clear implementation direction and compliance with the new certification criteria, and eliminated the certification requirement that every EHR Module be certified to the “privacy and security” certification criteria.

The Voluntary Edition proposed rule included proposals that focused on improving regulatory clarity, simplifying the certification of EHR Modules that are designed for purposes other than meeting requirements of the EHR Incentive Programs, and discontinuing the use of the Complete EHR definition. As noted above, we issued the 2014 Edition Release 2 final rule to complete the rulemaking for the Voluntary Edition proposed rule. The 2014 Edition Release 2 final rule discontinued the “Complete EHR” certification concept beginning with the proposed 2015 Edition, adopted an updated standard (ISO/IEC 17065) for the accreditation of ONC-ACBs, and adopted the “ONC Certified HIT” certification and design mark for required use by ONC-ACBs under the ONC Health IT Certification Program.

As noted above, on March 30, 2015, the Secretary published the Proposed Rule which, in addition to proposing the 2015 Edition, proposed revisions to the ONC Health IT Certification Program.

III. Provisions of the Proposed Rule Affecting Standards, Implementation Specifications, and Certification Criteria

A. 2015 Edition Health IT Certification Criteria

This rule finalizes new, revised, and unchanged certification criteria that establish the capabilities and related standards and implementation specifications for the certification of health IT, including EHR technology. We refer to these new, revised, and unchanged certification criteria as the “2015 Edition health IT certification criteria” and have added this term and its definition to § 170.102. As noted in the Executive Summary, we also refer to

these criteria as the “2015 Edition” in this preamble. We codified the 2015 Edition in § 170.315 to set them apart from other editions of certification criteria and make it easier for stakeholders to quickly determine the certification criteria included in the 2015 Edition.

In the Proposed Rule, we identified the 2015 Edition certification criteria as new, revised, or unchanged in comparison to the 2014 Edition. In the 2014 Edition final rule we gave meaning to the terms “new,” “revised,” and “unchanged” to both describe the differences between the 2014 Edition certification criteria and the 2011 Edition certification criteria, as well as establish what certification criteria in the 2014 Edition were eligible for gap certification (see 77 FR 54171, 54202, and 54248). Given that beginning with the 2015 Edition, “Complete EHR” certifications will no longer be issued (see also 79 FR 54443–45) and that we proposed to make the ONC Health IT Certification Program more open and accessible to other health care/practice settings, we also proposed to give new meaning to these terms for the purpose of a gap certification analysis as so specified:

- “New” certification criteria are those that as a whole only include capabilities never referenced in previously adopted certification criteria editions and to which a Health IT Module presented for certification to the 2015 Edition could have never previously been certified. As a counter example, the splitting of a 2014 Edition certification criterion into two criteria as part of the 2015 Edition would not make those certification criteria “new” for the purposes of a gap certification eligibility analysis.

- “Revised” certification criteria are those that include within them capabilities referenced in a previously adopted edition of certification criteria as well as changed or additional new capabilities; and to which a Health IT Module presented for certification to the 2015 Edition could *not* have been previously certified to all of the included capabilities.

- “Unchanged” certification criteria are those that include the same capabilities as compared to prior certification criteria of adopted editions; and to which a Health IT Module presented for certification to the 2015 Edition could have been previously certified to all of the included capabilities.

Comments. While we received no specific comments on these terms, we received comments both supporting and opposing the adoption of certification

criteria that go beyond specifically supporting an objective and measure under the EHR Incentive Programs.

Response. We continue to maintain the same meanings for the terms “new,” “revised,” and “unchanged” as described in the Proposed Rule with a slight modification to the meaning of “unchanged” to state that “unchanged” certification criteria are certification criteria that include the same *or less* of the same capabilities as compared to prior certification criteria of adopted editions. We refer readers to section III.A.4 (“2015 Edition Gap Certification

Eligibility Table”) of this preamble for a complete description of gap certification and the identification of 2015 Edition certification criteria eligible for gap certification. In sum, “unchanged” criteria are eligible for gap certification. For health IT previously certified to the 2011 or 2014 Edition certification criteria, this permits, where applicable, the use of prior test results for certification to the 2015 certification criteria. This creates efficiencies and substantially reduces burden.

As described in the Proposed Rule and Executive Summary of this final

rule as well as discussed in more detail in section IV.B of this preamble, we believe the availability and use of certified health IT for other use cases and health care settings beyond the EHR Incentive Programs has significant value. Therefore, we have adopted certification criteria that support those purposes. Table 2 below provides an overview of certification criteria adopted in this final rule as compared to the certification criteria proposed in the Proposed Rule and the adopted 2014 Edition.

TABLE 2—2015 EDITION HEALTH IT CERTIFICATION CRITERIA

Not Adopted Proposed Criteria (14)

Vital Signs
Image Results
Family Health History—Pedigree
Patient List Creation
Electronic Medication Administration Record
Decision Support—Knowledge Artifact
Decision Support—Service
Incorporate Laboratory Tests and Values/Results
Transmission of Laboratory Test Reports
Accessibility Technology
SOAP Transport and Security Specification and XDR/XDM for Direct Messaging
Healthcare Provider Directory—Query Request
Healthcare Provider Directory—Query Response
Electronic Submission of Medical Documentation

Unchanged Criteria as Compared to the 2014 Edition (Gap Certification Eligible) (16)

Computerized Provider Order Entry (CPOE)—Medications
CPOE—Laboratory
CPOE—Diagnostic Imaging
Drug-Drug, Drug-Allergy Interaction Checks for CPOE
Medication List
Medication Allergy List
Drug-Formulary and Preferred Drug List Checks
Smoking Status
Authentication, Access Control, Authorization
Audit Report(s)
Amendments
Automatic Access Time-Out
Emergency Access
End-User Device Encryption
Accounting of Disclosures
Transmission to Public Health Agencies—Reportable Laboratory Tests and Values/
Results

Revised Criteria as Compared to the 2014 Edition (25)

Demographics
Problem List
Clinical Decision Support
Family Health History
Patient-Specific Education Resources
Transitions of Care
Clinical Information Reconciliation and Incorporation
Electronic Prescribing
Data Export
Clinical Quality Measures—Record and Export
Clinical Quality Measures—Import and Calculate
Clinical Quality Measures—Report
View, Download, and Transmit to 3rd Party
Transmission to Immunization Registries
Transmission to Public Health Agencies—Syndromic Surveillance
Transmission to Cancer Registries
Automated Numerator Recording
Automated Measure Calculation

TABLE 2—2015 EDITION HEALTH IT CERTIFICATION CRITERIA—Continued

Safety-enhanced Design Quality Management System Auditable Events and Tamper-Resistance* Integrity* Secure Messaging* Direct Project* Direct Project, Edge Protocol, and XDR/XDM*	
New Criteria as Compared to the 2014 Edition (19)	
Implantable Device List Social, Psychological, and Behavioral Data Data Segmentation for Privacy—Send Data Segmentation for Privacy—Receive Care Plan Common Clinical Data Set Summary Record—Create	New criteria based on request for comment in the Proposed Rule.
Common Clinical Data Set Summary Record—Receive Clinical Quality Measures—Filter Trusted Connection	New for privacy and security certification framework and API approach.
Auditing Actions on Health Information	New for privacy and security certification framework and API approach.
Patient Health Information Capture. Transmission to Public Health Agencies—Electronic Case Reporting. Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting. Transmission to Public Health Agencies—Health Care Surveys. Consolidated CDA Creation Performance. Application Access—Patient Selection	Split the proposed API criterion into three criteria based on public comments. Application Access—Data Category Request.
Application Access—All Data Request Accessibility—centered Design.	

* The criterion was proposed as unchanged, but has been adopted as revised in this final rule.

We proposed that readers should interpret the following terms used in the 2015 Edition with the same meanings we adopted in the 2014 Edition final rule (77 FR 54168–54169), in response to comment: “User,” “record,” “change,” “access,” “incorporate,” “create,” and “transmit,” but apply to all health IT, not just “EHR technology.” For the term “incorporate,” we also proposed that readers should interpret the term as we further explained it under the “transitions of care” certification criterion (77 FR 54218) in the 2014 Edition final rule and in the Voluntary Edition proposed rule (79 FR 10898). We proposed that the scope of a 2015 Edition certification criterion was 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 the 2015 Edition 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 proposed 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 2015 Edition certification

criteria (*i.e.*, “export summary,” “transition of care/referral summary,” “ambulatory summary,” and “inpatient summary.”) We received no specific comments on these proposals and have adopted these meanings and approaches for certification to the 2015 Edition. As with the adoption of the 2011 and 2014 editions of certification criteria (see the introductory text to §§ 170.302, 170.304, 170.306, and 170.314), all capabilities mentioned in certification criteria are expected to be performed electronically, unless otherwise noted. Therefore, we no longer include “electronically” in conjunction with each capability included in a certification criterion under § 170.315 because the introductory text to § 170.315 (which covers all the certification criteria included in the section) clearly states that health IT must be able to *electronically* perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in the part. Health IT certified to the 2015 Edition certification criteria and associated standards and implementation specifications can be implemented as part of an EP’s, eligible hospital’s, or

CAH’s CEHRT and used to demonstrate meaningful use (as identified in Table 4 of section III.A.3 below). We note that Table 4 also identifies certification criteria that are mandatory and conditional certification requirements for Health IT Modules, such as safety-enhanced design (conditional), and quality management system (mandatory), accessibility-centered design (mandatory), and privacy and security certification criteria (conditional). To note, we use the term mandatory to mean that all Health IT Modules must be certified to the certification criterion (see also § 170.550(g)(2) and (3)). Conditional means that certification to the certification criterion (e.g., the “Consolidated CDA creation performance,” “safety-enhanced design,” “automatic access timeout,” or “integrity” certification criterion) depends on what other certification criteria a Health IT Module is presented for certification to (see § 170.550(g)(1) and (4) and § 170.550(f)). For more information on “conditional” certification related to privacy and security, we also refer readers to section IV.C.1 (“Privacy and Security”) of this preamble.

Health IT certified to the 2015 Edition certification criteria and associated standards and implementation specifications can also be used to meet other HHS program requirements (e.g., Medicare chronic care management services) or private sector requirements (e.g., The Joint Commission performance measurement initiative (“ORYX” vendor)). We refer readers to section IV.B.4 of this preamble for further programs that reference the use of certified health IT.

1. Applicability

Section 170.300 establishes the applicability of subpart C—Certification Criteria for Health Information Technology. We proposed to revise paragraph (d) of § 170.300 to add in a reference to § 170.315 and revise the parenthetical in the paragraph to say “i.e., apply to any health care setting” instead of “i.e., apply to both ambulatory and inpatient settings.”

We received no comments on these specific proposed revisions and have adopted the proposed revisions. As noted in the Proposed Rule, these revisions clarify which specific capabilities *within* a certification criterion included in § 170.315 have general applicability (i.e., apply to any health care setting) or apply only to an inpatient setting or an ambulatory setting. The revision to change the language of the parenthetical aligns with our approach to make the ONC Health IT Certification Program more agnostic to health care settings and accessible to health IT that supports care and practice settings beyond the ambulatory and inpatient settings. We refer readers to section IV.B of this preamble for a detailed discussion of modifications to the ONC Health IT Certification Program responses to public comments received on the proposed modifications.

We note that, with the 2015 Edition, we no longer label an entire certification criterion as either optional or ambulatory/inpatient (at the second paragraph level of § 170.315). For example, the 2015 Edition certification criterion for transmission to cancer registries is simply “transmission to cancer registries” instead of “optional—ambulatory setting only—transmission to cancer registries.” Similarly, the 2015 Edition certification criterion for “accounting of disclosures” is simply “accounting of disclosures” instead of “optional—accounting of disclosures.” These simplifications are possible given that, beginning with the 2015 Edition certification criteria, “Complete EHR” certifications will no longer be issued (see 79 FR 54443–45). Therefore, there is no longer a need to designate an

entire certification criterion in this manner. Again, this approach also supports our goal to make the ONC Health IT Certification Program more agnostic to health care settings and accessible to health IT that supports care and practice settings beyond the ambulatory and inpatient settings. We note that we still use “optional,” “inpatient setting only,” and “ambulatory setting only” designations within certification criteria to provide flexibility and reduce burden where feasible and appropriate.

We proposed to replace the term “EHR technology” in paragraphs (d)(1) and (d)(2) of § 170.300 with “health IT” to align with our approach to make the ONC Health IT Certification Program more clearly open to the certification of all types of health IT. We received no comments on this specific proposal and have replaced “EHR technology” with “health IT” in the referenced paragraphs. Again, we refer readers to section IV.B of this preamble for a detailed discussion of modifications to the ONC Health IT Certification Program and responses to public comments received on the proposed modifications.

2. Standards and Implementation Specifications

a. National Technology Transfer and Advancement Act

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–119⁵ require the use of, 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 final rule, we refer to voluntary consensus standards, except for:

- The standards adopted in § 170.202. (These industry standards were developed by groups of industry stakeholders committed to advancing the Direct Project,⁶ which included initiatives under the Standards and Interoperability (S&I) Framework.⁷ These groups used consensus processes

⁵ http://www.whitehouse.gov/omb/circulars_a119.

⁶ <http://www.healthit.gov/policy-researchers-implementers/direct-project>.

⁷ <http://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework>.

similar to those used by voluntary consensus standards bodies.);

- The standards adopted at § 170.205(d)(4) and (e)(4) for reporting of syndromic surveillance and immunization information to public health agencies, respectively (These standards go through a process similar within the public health community to those used by other industry stakeholders and voluntary consensus standards bodies.);

- The standard adopted at § 170.207(f)(2) for race and ethnicity; and

- Certain standards related to the protection of electronic health information adopted in § 170.210.

We are aware of no voluntary consensus standard that would serve as an alternative to these standards for the purposes that we have identified in this final rule.

b. Compliance With Adopted Standards and Implementation Specifications

In accordance with Office of the Federal Register regulations related to “incorporation by reference,” 1 CFR part 51, which we follow when we adopt proposed standards and/or implementation specifications in a final rule, the entire standard or implementation specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard and implementation specification includes the entire document unless we specify otherwise. For example, for the Health Level Seven (HL7) Implementation Guide (IG) for CDA Release 2: National Health Care Surveys (NHCS), Release 1 adopted in this final rule, health IT certified to the certification criterion referencing this IG will need to demonstrate compliance with all mandatory elements and requirements of the IG. If an element of the IG is optional or permissive in any way, it will remain that way for testing and certification unless we specified otherwise in regulation. In such cases, the regulatory text preempts the permissiveness of the IG.

c. “Reasonably Available” to Interested Parties

The Office of the Federal Register has established new requirements for materials (e.g., standards and implementation specifications) that agencies incorporate by reference in the **Federal Register** (79 FR 66267; 1 CFR 51.5(b)). To comply with these requirements, in section V (“Incorporation by Reference”) of this

preamble, we provide summaries of, and uniform resource locators (URLs) to, the standards and implementation specifications we have adopted and incorporated by reference in the **Federal Register**. To note, we also provide relevant information about these standards and implementation specifications throughout this section of the preamble (section III), including URLs.

“Minimum Standards” Code Sets

In the Proposed Rule, we proposed to adopt newer versions of four previously adopted minimum standards code sets for the 2015 Edition. The code sets proposed were: The September 2014 Release of the U.S. Edition of SNOMED CT®, LOINC® version 2.50, the February 2, 2015 monthly version of RxNorm, and the February 2, 2015 version of the CVX code set. We also proposed to adopt two new minimum standards code sets (the National Drug Codes (NDC)—Vaccine Codes, updates through January 15, 2015 and the “Race & Ethnicity—CDC” code system in the PHIN Vocabulary Access and Distribution System (VADS) Release 3.3.9 (June 17, 2011)). We reiterated, as we have previously articulated (77 FR 54170), the adoption of newer versions improve interoperability and health IT implementation, while creating little additional burden through the inclusion of new codes. We further stated that, as many of these minimum standards code sets are updated frequently throughout the year, we would consider whether it may be more appropriate to adopt a version of a minimum standards code set that is issued before we publish a final rule for the Proposed Rule.

Comments. A number of commenters were supportive of the proposal to adopt more recent versions of the U.S. Edition of SNOMED CT®, LOINC®, RxNorm, and the CVX code set. Commenters supported adoption of NDC codes for vaccines, but also recommended we adopt the MVX codes for vaccine manufacturer as part of this list. One commenter requested identification of the steward for the PHIN VADS “Race & Ethnicity—CDC” code system, noting that it did not appear to have been updated since 2007. This commenter also requested verification that the code set has been reviewed on a regular basis.

A few commenters suggested that we do not specify an exact version and release of a standard (e.g., allow for adoption of version/release 1.x of the HL7 Implementation Guide for CDA

Release 2: National Health Care Surveys (NHCS) where “x” could be any version/release within the version/release 1 family). Another commenter suggested that we consider adopting a “rolling” upgrade cycle for all standardized code systems and value sets. Specifically, the commenter recommended that a certified Health IT Module should not be more than two versions behind the most currently released version of the code system or value set. Commenters also suggested that the vocabulary code set versions in the Proposed Rule are now outdated and have since been updated per a regular update cycle. Commenters suggested we adopt these more recent versions of these vocabulary code sets as they provide the most up-to-date clinical information for clinical relevance and interoperability.

Response. As many of the proposed minimum standards code sets are updated frequently throughout the year, we considered whether it was more appropriate to adopt versions of minimum standards code sets that were issued after the Proposed Rule and before we published this final rule. In making such determination, as we have done with prior finalized versions of minimum standards code sets, we gave consideration to whether these newer versions included any new substantive requirements and their effects on interoperability. We have found no negative effects on interoperability with the newer versions we have adopted as compared to the proposed versions. Rather, these newer versions will further support and improve the structured recording of data. To note, the adopted newer version of a minimum standards code set will serve as the baseline for certification. As with all adopted minimum standards code sets, health IT can be certified to newer versions of the adopted baseline version minimum standards code sets for purposes of certification, unless the Secretary specifically prohibits the use of a newer version (see § 170.555 and 77 FR 54268).

We have adopted newer versions of four 2014 Edition minimum standards code sets in this final rule for the 2015 Edition. These code sets are the September 2015 Release of the U.S. Edition of SNOMED CT®, LOINC® version 2.52, the September 8, 2015 monthly version of RxNorm, and the August 17, 2015 version of the CVX code set. We have also adopted three new minimum standards code sets.

These code sets are the National Drug Codes (NDC)—Vaccine NDC Linker, updates through August 17, 2015; the CDC Race and Ethnicity Code Set Version 1.0 (March 2000);⁸ and the Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015.

We have not adopted MVX codes for vaccine manufacturers as detailed further in the discussion on the “transmission to immunization registries” certification criterion in section III.A.3 of the preamble. Therefore, we do not see a need to include MVX codes in this list of code sets.

We confirm that CDC continues to steward the CDC Race and Ethnicity Code Set, Version 1.0 (March 2000). We also confirm that we have reviewed this version and believe it is appropriate to adopt it as the minimum standard code set for race and ethnicity. Any updates to the code set, including the issuance of newer versions, are within the oversight of the CDC.

As we stated in the 2014 Edition final rule (77 FR 54169–54170), the Office of the Federal Register regulations related to “incorporation by reference” are limited to a specific version that is approved rather than future versions or revisions of a given publication. Thus, we do not include regulation language that refers to a version/release as, for example “Version/Release 1.X” when “X” remains variable. Further, to remain in compliance with the Administrative Procedure Act and address any potential interoperability concerns, we would need to issue regulations to adopt a newer version minimum standards code set as a “baseline” standard and cannot require health IT developers to upgrade on a rolling basis.

e. Object Identifiers (OIDs) for Certain Code Systems

We are providing the following table (Table 3) of OIDs for certain code systems to assist health IT developers in the proper identification and exchange of health information coded to the vocabulary standards referenced in this final rule.

⁸ We have more specifically identified the CDC Race and Ethnicity code set as compared to the identification in the Proposed Rule. We note this code set remains part of the PHIN Vocabulary Access and Distribution System (VADS) Release 3.3.9. <http://www.cdc.gov/phn/resources/vocabulary/index.html>.

TABLE 3—CODE SYSTEM OBJECT IDENTIFIERS (OIDS)

Code system OID	Code system name
2.16.840.1.113883.6.96	IHTSDO SNOMED CT®.
2.16.840.1.113883.6.1	LOINC®.
2.16.840.1.113883.6.88	RxNorm.
2.16.840.1.113883.12.292	HL7 Standard Code Set CVX-Vaccines Administered.
2.16.840.1.113883.6.69	National Drug Code Directory.
2.16.840.1.113883.6.8	Unified Code of Units of Measure (UCUM ⁹).
2.16.840.1.113883.6.13	Code on Dental Procedures and Nomenclature (CDT).
2.16.840.1.113883.6.4	International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS).
2.16.840.1.113883.6.238	CDC Race and Ethnicity Code Set Version 1.0 (March 2000).
2.16.840.1.113883.6.316	Tags for Identifying Languages—Request for Comment (RFC) 5646 (preferred language).
2.16.840.1.113883.6.101	Healthcare Provider Taxonomy.

f. Subpart B—Standards and Implementation Specifications for Health Information Technology

We proposed to remove the term “EHR Modules” from § 170.200 and add in its place “Health IT Modules” We proposed to remove the term “EHR technology” from § 170.210 and add in its place “health IT.” We noted that these proposals were consistent with our overall approach to this rulemaking as discussed in the Proposed Rule Executive Summary and recited in this final rule’s Executive Summary. We received no comments on these specific proposals and have adopted these proposals. We refer readers to section IV.B of this preamble for a detailed discussion of modifications to the ONC Health IT Certification Program and responses to public comments received on the proposed modifications.

3. Adopted Certification Criteria

We discuss the certification criteria that we have adopted as part of the 2015 Edition in this section. We discuss each

certification criterion in the chronological order in which it would appear in the CFR. In other words, the preamble that follows discusses the adopted certification criteria in § 170.315(a) first, then § 170.315(b), and so on through section (h). Due to certain proposed certification criteria not being adopted as well as further consideration of proper categorization of criteria, the designation of some criteria within § 170.315 has changed in comparison to the Proposed Rule (*e.g.*, the 2015 Edition “smoking status” criterion has been codified in § 170.315(a)(11) instead of proposed (a)(12) and the 2015 Edition “patient health information capture” criterion has been codified in § 170.315(e)(3) instead of proposed (a)(19)).

We note that we have restructured the regulatory text of certification criteria to remove the use of “or” in many places where it was proposed to indicate certification optionality. We have replaced it with language that we believe will better convey that same optionality. This restructuring of the

regulatory text will provide further clarity regarding when a health IT developer has flexibility to select one of two or more options for certifying its Health IT Module as compared to when it is expected that the Health IT Module demonstrate all listed methods for certification. This restructuring, by itself, did not alter any of the proposed certification criteria requirements.

Table 4 below identifies the 2015 Edition certification criteria associated with the EHR Incentive Programs Stage 3 as finalized in EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**. While these certification criteria can be used to support other use cases and health care settings beyond the EHR Incentive Programs, we have also adopted additional 2015 health IT certification criteria that support other specific use cases and health care settings. These criteria were listed in Table 2 and are discussed in this section of the preamble.

⁹ Copyright© 1998–2013, Regenstrief Institute, Inc. and the UCUM Organization. All rights reserved.

Table 4. 2015 Edition Health IT Certification Criteria Associated with the EHR Incentive Programs Stage 3			
CFR Section 170.315	Certification Criterion	Relationship to the CEHRT¹⁰ Definition and Stage 3 Objectives¹¹	Health IT Module Certification Requirements
(a)(1)	Computerized Provider Order Entry (CPOE) – Medications ¹²	Specifically included in the CEHRT definition Associated with Objective 4	
(a)(2)	CPOE – Laboratory ¹³	Specifically included in the CEHRT definition Associated with Objective 4	
(a)(3)	CPOE – Diagnostic Imaging ¹⁴	Specifically included in the CEHRT definition Associated with Objective 4	
(a)(4)	Drug-Drug, Drug-Allergy Interaction Checks for CPOE	Associated with Objective 3	
(a)(5)	Demographics	Specifically included in the CEHRT definition	
(a)(6)	Problem List	Specifically included in the CEHRT definition	
(a)(7)	Medication List	Specifically included in the CEHRT definition	
(a)(8)	Medication Allergy List	Specifically included in the CEHRT definition	
(a)(9)	Clinical Decision Support	Specifically included in the CEHRT definition Associated with Objective 3	
(a)(10)	Drug-Formulary and Preferred Drug List Checks	Associated with Objective 2	
(a)(11)	Smoking Status	Specifically included in the CEHRT definition	
(a)(12)	Family Health History	Specifically included in the CEHRT definition	

¹⁰ The EHR Incentive Programs CEHRT definition includes the criteria adopted in the 2015 Edition Base EHR definition. These criteria are identified in this table as specifically included in CEHRT definition, as are other criteria specifically included in the CEHRT definition but are not part of the 2015 Edition Base EHR definition. For more information on the 2015 Edition Base EHR definition, please see section III.B.1 of this final rule's preamble. For more details on the CEHRT definition, please see the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

¹¹ Criteria "associated with objectives" support requirements of the EHR Incentive Programs to use certified EHR technology to meet objectives. For further information on these requirements, please see the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

¹² Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).

¹³ Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).

¹⁴ Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).

(a)(13)	Patient-Specific Education Resources	Associated with Objective 5	
(a)(14)	Implantable Device List	Specifically included in the CEHRT definition	
(b)(1)	Transitions of Care	Specifically included in the CEHRT definition Associated with Objective 7	
(b)(2)	Clinical Information Reconciliation and Incorporation	Associated with Objective 7	
(b)(3)	Electronic Prescribing	Associated with Objective 2	
(b)(6)	Data Export	Specifically included in the CEHRT definition	
(c)(1)	Clinical Quality Measures – Record and Export	Specifically included in the CEHRT Definition	
(c)(2)	Clinical Quality Measures – Import and Calculate	Specifically included in the CEHRT Definition	
(c)(3)	Clinical Quality Measures – Report	Specifically included in the CEHRT Definition	
(e)(1)	View, Download, and Transmit to 3 rd Party	Associated with Objective 5 Associated with Objective 6	
(e)(2)	Secure Messaging	Associated with Objective 6	
(e)(3)	Patient Health Information Capture	Specifically included in the CEHRT definition Associated with Objective 6	
(f)(1)	Transmission to Immunization Registries	Associated with Objective 8 ¹⁵	
(f)(2)	Transmission to Public Health Agencies – Syndromic Surveillance	Associated with Objective 8	
(f)(3)	Transmission to Public Health Agencies – Reportable Laboratory Tests and Values/Results	Associated with Objective 8	
(f)(4)	Transmission to Cancer Registries	Associated with Objective 8	
(f)(5)	Transmission to Public Health Agencies – Electronic Case Reporting	Associated with Objective 8	
(f)(6)	Transmission to Public Health Agencies – Antimicrobial Use and Resistance Reporting	Associated with Objective 8	
(f)(7)	Transmission to Public Health Agencies – Health Care Surveys	Associated with Objective 8	
(g)(1)	Automated Numerator Recording	Specifically included in the CEHRT definition	
(g)(2)	Automated Measure Calculation	Specifically included in the CEHRT definition	
(g)(7)	Application Access – Patient Selection	Specifically included in the CEHRT definition	

¹⁵ For the public health certification criteria in § 170.315(f), health IT will only need to be certified to those criteria that are required to meet the measures the provider intends to report on to meet Objective 8: Public Health and Clinical Data Registry Reporting.

		Associated with Objective 5 Associated with Objective 6	
(g)(8)	Application Access – Data Category Request	Specifically included in the CEHRT definition Associated with Objective 5 Associated with Objective 6	
(g)(9)	Application Access – All Data Request	Specifically included in the CEHRT definition Associated with Objective 5 Associated with Objective 6	
(h)(1)	Direct Project ¹⁶	Specifically included in the CEHRT definition	
(h)(2)	Direct Project, Edge Protocol, and XDR/XDM ¹⁷	Specifically included in the CEHRT definition	
(g)(4)	Quality Management System		Mandatory
(g)(5)	Accessibility-Centered Design		Mandatory
(d)(1)	Authentication, Access Control, Authorization		Conditional
(d)(2)	Auditable Events and Tamper-Resistance		Conditional
(d)(3)	Audit Report(s)		Conditional
(d)(4)	Amendments		Conditional
(d)(5)	Automatic Access Time-Out		Conditional
(d)(6)	Emergency Access		Conditional
(d)(7)	End-User Device Encryption		Conditional
(d)(8)	Integrity		Conditional
(d)(9)	Trusted Connection		Conditional
(d)(10)	Auditing Actions on Health Information		Conditional
(g)(3)	Safety-Enhanced Design		Conditional
(g)(6)	Consolidated CDA Creation Performance		Conditional
Key			
<u>Mandatory</u> : All Health IT Modules must be certified to the certification criterion.			
<u>Conditional</u> : A Health IT Module is certified to the certification criterion depending on the other certification criteria the Health IT Module is presented for certification to.			

• *Computerized Provider Order Entry*

We proposed to adopt three separate 2015 computerized provider order entry (CPOE) certification criteria based on the clinical purpose (*i.e.*, medications, laboratory, and diagnostic imaging), which was consistent with the 2014 Edition CPOE certification criteria we adopted in the 2014 Edition Release 2 final rule (79 FR 54435–36).

Comments. We received only a few comments on this proposed approach, all which expressed support for separating the functionality based on clinical purpose.

Response. We have adopted separate CPOE certification criteria based on clinical purposes that are described in more detail below.

We requested comment on whether we should specify, for the purposes of testing and certification to the 2015 Edition CPOE criteria, certain data elements that a Health IT Module must be able to include in a transmitted order. In particular, we requested comment on whether a Health IT Module should be able to include any or all of the following data elements: secondary diagnosis codes; reason for order; and comment fields entered by the ordering provider, if they are provided to the ordering provider in their order entry screen. We also requested comment on whether there are any other data elements that a Health IT Module should be able to include as part of an order for the purposes of testing and certification.

Comments. Most commenters opposed the inclusion of specific data elements for certification. These commenters most often cited burden on health IT developers and concern that new data elements might lead to inefficient workflow for the order entry process as reasons for not including additional data elements. Some commenters expressed support for the inclusion of additional data elements mentioned in the Proposed Rule, but varied in their support for the specific data elements that should we included. These commenters did, however, agree that the “reason for order” data element was a data element that should be included with an order.

Response. We acknowledge the lack of agreement as to what data elements

should be required for certification, but also the support for the “reason for order” data elements. With consideration of commenters concerns about burden and workflow inefficiencies, we have adopted the “reason for order” data element as an optional certification provision in each of the three CPOE certification criteria. We agree with commenters that the reason for an order data element has value. The designation of this provision as optional in all three criteria gives flexibility to health IT developers as they consider certification of their health IT and providers as they consider what certified health IT to purchase.

• *Computerized Provider Order Entry—Medications*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(1) (Computerized provider order entry—medications)

We proposed to adopt a 2015 Edition CPOE certification criterion specific to medication ordering that was unchanged in comparison to the 2014 Edition CPOE—medications criterion adopted at § 170.314(a)(18) as well as § 170.314(a)(1)(i). The proposed criterion does not reference any standards or implementation specifications.

Comments. Commenters overwhelmingly recommended that this criterion remain unchanged. A few commenters requested clarifications regarding the designation of authorized CPOE users and the proper counting of CPOE orders for the purposes of meeting the associated meaningful use objective and measure.

Response. We thank commenters for their support and have adopted this criterion as unchanged. As noted above, we have, however, adopted the “reason for order” data element as an *optional* provision within this criterion. For questions related to the EHR Incentive Programs (*i.e.*, the designation of authorized CPOE users and the proper counting of CPOE order for the purposes of meeting the associated meaningful use objective and measure), we refer readers to CMS and the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

• *Computerized Provider Order Entry—Laboratory*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(2) (Computerized provider order entry—laboratory)

We proposed to adopt a 2015 Edition CPOE certification criterion specific to laboratory ordering that was revised in comparison to the CPOE—laboratory criterion adopted at § 170.314(a)(19) as well as § 170.314(a)(1)(ii). For the ambulatory setting, we proposed that this criterion would include the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders (LOI) from EHR, Draft Standard for Trial Use, Release 2—US Realm (“Release 2”). We proposed to adopt the most recent version of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, (also referred to as the “electronic Directory of Services (eDOS) IG”) for certification to all health care settings. We also proposed to require that a Health IT Module use, at a minimum, version 2.50 of Logical Observation Identifiers Names and Codes (LOINC[®]) as the vocabulary standard for laboratory orders.

Comments. Commenters stated that the LOIs and eDOS IGs were not ready for implementations, but acknowledged the significant progress being made in developing standards for laboratory ordering and the harmonizing of laboratory-related IGs.

Response. With consideration of comments, we have determined not to adopt any standards for this certification criterion. We have, however, adopted the “reason for order” data element as an *optional* provision within this criterion. We have made the determination to keep this criterion “functional” at this time based on a number of factors, including (among other aspects) that the best versions of the IGs that could be associated with this criterion were not sufficiently ready. That being said, we believe that the LOI and eDOS IGs show great promise in improving laboratory interoperability and could potentially result in significant cost savings to the industry at large. Accordingly, we remain committed to continued collaboration with stakeholders to support the widespread adoption of these IGs, including the development of testing tools and pilots where necessary and feasible.

• *Computerized Provider Order Entry—Diagnostic Imaging*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(3) (Computerized provider order entry—diagnostic imaging)

We proposed to adopt a 2015 Edition CPOE certification criterion specific to diagnostic imaging ordering that was unchanged in comparison to the 2014

Edition CPOE—diagnostic imaging criterion adopted at § 170.314(a)(20) as well as § 170.314(a)(1)(iii). The proposed criterion does not reference any standards or implementation specifications. We also proposed to adopt the title of “diagnostic imaging,” which is the title we gave to the 2014 Edition version of this certification criterion in the 2014 Edition Release 2 final rule (79 FR 54436).

Comments. Commenters overwhelmingly recommended that this criterion remain unchanged. A few commenters recommended we add functionality to this criterion, including the required use of a standard such as Digital Imaging and Communications in Medicine (DICOM) to support radiology.

Response. We thank commenters for their support and have adopted this criterion as unchanged. As noted above, we have, however, adopted the “reason for order” data element as an *optional* provision within this criterion. While we appreciate comments suggesting the inclusion of additional functionality, the recommended functionality is outside the scope of the proposed criterion. Therefore, we have not adopted the recommended functionality in this criterion. We also refer readers to our previous discussion of DICOM (77 FR 54173).

• *Drug-Drug, Drug-Allergy Interaction Checks for CPOE*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(4) (Drug-drug, drug-allergy interaction checks for CPOE)

We proposed to adopt a revised 2014 Edition “drug-drug, drug-allergy interaction checks” criterion (§ 170.314(a)(2)) to clarify that the capabilities included in this criterion are focused on CPOE. We proposed that a Health IT Module must record at least one action taken and by whom, and must generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks (DD/DAI). We explained that the benefits of recording user actions for DD/DAI interventions that assist with quality improvement and patient safety outweigh the development burden associated with this functionality. However, to address development concerns, we proposed that a Health IT Module must only record, at a minimum, one user action for DD/DAI checks; and asked for comment on focusing the requirement to record at least one user action taken for DD/DAI interventions on a subset of DD/DAI interventions and what sources we

should consider for defining this subset. We further noted that the proposed criterion does not establish the uses for the “user action” information, who should be able to view the information, or who could adjust the capability. We also sought comment on requiring functionality that would inform a user of new or updated DD/DAI when the medication or medication allergy lists are updated.

Comments. We received a few comments supporting our proposed clarification that this criterion focused on CPOE, but also suggestions that this functionality could support other use cases, such as when medications are reviewed or medication or medication allergy lists are updated. We received mixed comments in response to the proposed additional “recording user response” functionality for this criterion. While many commenters supported the overall goal of interaction checking for quality improvement and patient safety, including functionality that would inform a user of new or updated DD/DAI, many commenters stated that current systems already provide a wide range of functionality to enable providers to document decisions concerning interaction warnings. These commenters stated that the proposed “recording user response” is not necessary for certification or for providers to satisfy objectives of the EHR Incentive Programs. Commenters requested the criterion remain eligible for gap certification. A few expressed overall agreement with the other functionality specified in this criterion, including the ability to adjust the severity level of interventions (*e.g.*, alerts) for drug-drug interaction checks.

Response. We have determined, based on public comments, to focus this certification criterion on CPOE and to not adopt the “recording user response” functionality. This approach is responsive to comments and will permit health IT developers to focus their efforts on functionality and requirements that support the goals outlined in the Executive Summary, including supporting the interoperability of health IT. To note, this criterion is eligible for gap certification.

- *Demographics*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(5) (Demographics)

We proposed to adopt a revised 2015 Edition “demographics” certification criterion in comparison to the 2014 Edition certification criterion (§ 170.314(a)(3)). We received comments

that focused on each of the specific data elements in the certification criterion. We have categorized and responded to these comments in a similar manner.

Sex

We proposed the requirement to record sex in accordance with HL7 Version 3 (“AdministrativeGender”) and a nullFlavor value attributed as follows: male (M); female (F); and unknown (UNK), and noted that HL7 Version 3 for recording sex would be required under the “Common Clinical Data Set” definition for certification to the 2015 Edition. In the Proposed Rule’s section III.B.3 (“Common Clinical Data Set”), we stated that this approach would become the method for capturing sex under the “Common Clinical Data Set” definition for certification to the 2015 Edition.

Comments. Commenters were generally supportive of recording sex in a structured manner. A few commenters suggested that we used other values, such as U or UN for undifferentiated. A few commenters also requested clarification on the proposed use of two different value sets (HL7 AdministrativeGender and NullFlavor).

Response. We appreciate the support for our proposal. We have adopted the requirement for recording sex as proposed. We clarify that this coding is intended to present birth sex. Therefore, we believe the use of the specified values and value sets is the most appropriate approach. It is also an approach that we believe poses the least burden and most health IT developers are using these values and value sets.

Race and Ethnicity

We proposed the requirement to record each one of a patient’s races and ethnicities in accordance with, at a minimum, the “Race & Ethnicity—CDC” code system in the PHIN Vocabulary Access and Distribution System (VADS), Release 3.3.9¹⁸ and aggregate each one of a patient’s races and ethnicities to the categories in the OMB standard for race and ethnicity. We explained that a Health IT Module must be able to record each one of a patient’s races and ethnicities using any of the 900 plus concepts in the “Race & Ethnicity—CDC” code system, and noted that health IT developers and health care providers could determine the appropriate user interface implementation in a given setting. The Proposed Rule section III.A.2.d (“Minimum Standards” Code Sets) discussed the adoption of the “Race &

Ethnicity—CDC” code system in PHIN VADS as a minimum standards code set and Release 3.3.9, or potentially a newer version if released before this final rule, as the baseline for certification to the 2015 Edition. To note, the Proposed Rule section III.B.3 “Common Clinical Data Set” also discussed adopting the Race & Ethnicity—CDC” code system in PHIN VADS (at a minimum, Release 3.3.9) and the OMB standard as the race and ethnicity standards under the “Common Clinical Data Set” definition for certification to the 2015 Edition.

Comments. A majority of commenters supported our proposal to require a Health IT Module to be able to capture granular patient race and ethnicity data. Some commenters questioned the necessity for such granular race and ethnicity capture because it was not required for the EHR Incentive Programs or another identified purpose, with one commenter recommending that this be a future certification requirement.

Commenters expressed concerns about user interfaces in relation to the over 900 concepts for race and ethnicity in PHIN VADS, including concern over how many concepts should be displayed for users. Similarly, commenters suggested that testing and certification should not be to all 900 concepts. A few commenters requested clarification on whether a health IT Module must be able to capture multiple races or ethnicities for a patient and the appropriate method for capturing when a patient declines to provide race or ethnicity information.

Response. We thank commenters for their support. We have adopted the race and ethnicity requirements as proposed, including the use of both the OMB and the CDC Race and Ethnicity standards. We believe that the structured granular recording of race and ethnicity can both improve patient care and support the elimination of health disparities whether or not currently required by the EHR Incentives Programs or another HHS program. By adopting these requirements, we ensure certified health IT has these capabilities and can make them available to providers. We clarify four points in response to comments. First, as mentioned in the Proposed Rule, a health IT developer and provider can best determine how the user interface is designed, including how many race and ethnicity values are displayed. Second, as mentioned above and in the Proposed Rule, a Health IT Module must be able to record each one of a patient’s races and ethnicities using any of the 900 plus concepts. For testing and certification, a Health IT Module would be tested to any of the 900 plus concepts at the discretion of the testing

¹⁸ <https://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.6.238#>.

body. Third, a Health IT Module would need to be capable of recording multiple races and/or ethnicities for a patient. This approach is consistent with the OMB standard. Fourth, a Health IT Module must be able to demonstrate that it can record whether a patient declined to provide information for all data specified in this certification criterion. We do not, however, specify for the purposes of certification how that data is specifically captured.

Preferred Language

In the Proposed Rule, we proposed to require the use of the Internet Engineering Task Force (IETF) Request for Comments (RFC) 5646¹⁹ standard for preferred language. We stated that RFC 5646 entitled “Tags for Identifying Languages, September 2009” is the coding system that is commonly used to encode languages on the web. We also noted that this standard is compatible with the C-CDA Release 2.0 (and C-CDA Release 2.1) and that other preferred language standards in use today can be efficiently mapped to it, such as ISO 639-1, 639-2, and 639-3. The Proposed Rule explained that the standard does not determine the way in which health care providers use the capability to record preferred language or the preferred language values they are presented with to select a patient’s preferred language. In the Proposed Rule’s section III.B.3 (“Common Clinical Data Set”), we stated that RFC 5646 would also become the preferred language standard under the “Common Clinical Data Set” definition for certification to the 2015 Edition.

Comments. Commenters were generally supportive of the adoption of the RFC 5646 standard. Some commenters (health IT developers) expressed opposition to the recording of preferred language in RFC 5646 due to the new burden it would create versus the perceived minimal value. One commenter suggested adopting ISO 639-3 instead of RFC 5646.

Response. We have adopted RFC 5646 as the preferred language standard for this criterion. As extensively discussed in the Proposed Rule (80 FR 16817), we believe this is the most appropriate standard for capturing a patient’s preferred language. It is compatible with the C-CDA Release 2.1 and other preferred language standards can be efficiently mapped to it, including ISO 639-1, 639-2, and 639-3. As mentioned in the Proposed Rule and clarified for other demographics data, a health IT developer and provider can best determine how the user interface is

designed, including how many preferred languages are displayed.

Preliminary Cause of Death and Date of Death

In the Proposed Rule, we proposed that, for the inpatient setting, a Health IT Module must include the functionality to record, change, and access the “date of death.” We stated that this functionality would be in addition to the requirement 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.

Comments. The majority of commenters supported this requirement. A few commenters requested clarification as to whether the preliminary cause of death was to be recorded consistent with either the SNOMED CT® or ICD-10-CM standards.

Response. We thank commenters for their support and have adopted this requirement as proposed. We clarify that the preliminary cause of death is not required to be recorded in accordance with a standard for the purposes of certification to this criterion as we did not propose such a requirement nor have we adopted one.

Sexual Orientation and Gender Identity (SO/GI)

We did not propose to include a requirement to capture a patient’s sexual orientation or gender identity as part of this criterion. Rather, we proposed the capture of SO/GI data as part of the proposed “social, psychological, and behavioral data” certification criterion.

Comments. We received a significant number of comments from providers, consumers/individuals, and health care coalitions strongly recommending that we consider including sexual orientation and gender identify as a component of the Base EHR definition (e.g., in the demographics certification criterion) or Common Clinical Data Set definition. These commenters suggested that there are mature vocabulary standards for representing SO/GI and there is strong clinical value in having this data to inform decisions about health care and treatment. Commenters indicated that by including SO/GI in the Base EHR or Common Clinical Data Set definitions, providers would be required to possess this functionality for participation in the EHR Incentive Programs, which could have a large impact for evaluating the quality of care provided to lesbian, gay, bisexual, and transgender (LGBT) communities.

Response. We thank commenters for their feedback. Given this feedback, the clinical relevance of capturing SO/GI, and the readiness of the values and vocabulary codes for representing this information in a structured way, we require that Health IT Modules enable a user to record, change, and access SO/GI to be certified to the 2015 Edition “demographics” certification criterion. By doing so, SO/GI is now included in the 2015 Edition Base EHR definition. The 2015 Edition Base EHR definition is part of the CEHRT definition under the EHR Incentive Programs. Therefore, providers participating in the EHR Incentive Programs will need to have certified health IT with the capability to capture SO/GI to meet the CEHRT definition in 2018 and subsequent years.

We note that like all information in the “demographics” criterion, certification does not require that a provider collect this information, only that certified Health IT Modules enable a user to do so. We believe including SO/GI in the “demographics” criterion represents a crucial first step forward to improving care for LGBT communities.

We have not included it in the Common Clinical Data Set at this time. We refer readers to section III.B.3 of this preamble for further discussion of the Common Clinical Data Set.

Comments. We received comments from a health care coalition that has partnered with and coordinated industry-development of the appropriate terminology to capture SO/GI for health care settings. The commenters suggested that we revise the proposed terminology for collecting SO/GI to use more appropriate language that reflects up-to-date, non-offensive terminology that will facilitate the goal of providing welcoming and affirming health care to LGBT individuals. As such, the commenters recommended that we retain the proposed SNOMED CT® and HL7 V3 codes but revise the description of some codes to use synonyms which reflect more appropriate language. The commenters noted that they have already submitted revisions to SNOMED CT® to include the synonyms for these terms. The commenters also noted that the core concepts of the codes remain the same.

Response. We thank the commenters for the suggestion and are proceeding with the recommendation to include use the revised terminology for collecting SO/GI. We refer readers to § 170.207(o)(1) and § 170.207(o)(2) for a full list of the code descriptors and codes for SO/GI, respectively.

Comments. One commenter recommended we consider including structured and coded questions for

¹⁹ <http://www.rfc-editor.org/info/rfc5646>.

soliciting SO/GI information as part of certification.

Response. While we thank the commenter for providing this recommendation, we do not believe that the suggested questions have not yet been scientifically validated for use in health care settings and, thus, have not adopted them. We do, however, believe that these questions are being used today in health care settings as “best practices,” and would suggest that health care providers and institutions decide whether to include these questions in the collection of SO/GI information. These “best practice” questions and the answers we have adopted are:

- Do you think of yourself as:
 - Straight or heterosexual;
 - Lesbian, gay, or homosexual;
 - Bisexual;
 - Something else, please describe.
 - Don't know.
- What is your current gender identity? (Check all that apply.)
 - Male;
 - Female;
 - Transgender male/Trans man/ Female-to-male;
 - Transgender female/Trans woman/ Male-to-female;
 - Genderqueer, neither exclusively male nor female;
 - Additional gender category/(or other), please specify.
 - Decline to answer.

Comments. One commenter recommended that we add another question and set of answers to collect assigned birth sex.

Response. We have not adopted this recommendation to collect assigned birth sex as suggested because we already require the capturing of birth sex as described under the “sex” section above.

- *Problem List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(6) (Problem list)

We proposed to adopt a 2015 Edition “problem list” certification criterion that was revised as compared to the 2014 Edition “problem list” certification criterion (§ 170.314(a)(5)) by requiring the September 2014 Release of the U.S. Edition of SNOMED CT® as the baseline version permitted for certification to this criterion. The Proposed Rule’s section III.A.2.d (“Minimum Standards” Code Sets) discussed our adoption of SNOMED CT® as a minimum standards code set and the adoption of the September 2014 Release (U.S. Edition), or potentially a newer version if released before this final rule, as the

baseline for certification to the 2015 Edition.

Comments. The majority of commenters supported the proposed certification criterion. A commenter suggested that instead of the full SNOMED CT® code system, the reference should be explicit to a concept and its value set relevant to this criterion, such as the “core” problem list. A commenter recommended requiring certification to the *most current* version of SNOMED CT®. Some commenters recommended that we require the use of the ICD–10–CM code set. These commenters noted that the code set is used for billing purposes and the required use of SNOMED CT® adds burden on providers and their staff due to the required use of two different systems.

A couple of commenters stated that the problem list should not be limited to the duration of a hospitalization because it may be needed when the patient is out of the hospital, suggesting “for the duration of an entire hospitalization” be struck from the criterion. Another commenter suggested that the distinction between inpatient and ambulatory records should be dropped in favor of a “patient” record stating that several major healthcare systems have dropped the distinction and are focusing on a patient problem list where one or more problems on the problem list are addressed in a particular encounter (outpatient visit or inpatient stay).

Commenters suggested that if this criterion was adopted as proposed that health IT developers should have the ability to attest that their health IT previously certified to the 2014 Edition “problem list” criterion meets the newer baseline version of SNOMED CT® for the purposes of testing and certification to this criterion.

Response. We have adopted this certification criterion as proposed, except that we have adopted a newer baseline version SNOMED CT® (September 2015 Release of the U.S. Edition) for the purposes of certification. We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for a more detailed discussion of our adoption of the September 2015 Release of the U.S. Edition of SNOMED CT® and for our reasons why we always adopt a baseline version of a vocabulary code set for certification instead of specifying certification must be to the “most current” version. As with the 2014 Edition, testing and certification will focus on a Health IT Module’s ability to enable a user to record, change, and access a patient’s problem list in accordance with SNOMED CT®.

This will enable a provider to choose any available and appropriate code in SNOMED CT® for a patient’s problems.

We did not propose as part of this criterion to test and certify a Health IT Module’s ability to enable a user to record, change, and access a patient’s active problem list and problem history across health care settings as this criterion is focused on the ambulatory and inpatient settings in support of the EHR Incentive Programs. We believe the use of “for the duration of an entire hospitalization” is appropriate for this criterion and refer readers to our detailed discussion of this determination in the 2014 Edition final rule (77 FR 54211–54212).

We agree with commenters that efficient testing and certification processes should be available to Health IT Modules previously certified to the 2014 Edition “problem list” criterion for certification to this criterion. Accordingly, we will consider such options, such as attestation, in developing the test procedure for this criterion and in issuing guidance to the ONC–AA and ONC–ACBs.

- *Medication List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(7) (Medication list)

We proposed to adopt a 2015 Edition “medication list” certification criterion that was unchanged as compared to the 2014 Edition “medication list” certification criterion (§ 170.314(a)(6)). To note, the proposed criterion does not reference any standards or implementation specifications.

Comments. The majority of commenters expressed support for this certification criterion as proposed. A few commenters suggested additional functionalities for this criterion. These suggestions included functionality to designate or mark medications as confidential or sensitive and include patient-generated data. One commenter recommended requiring that medications be recorded in accordance with RxNorm. A couple of commenters requested clarification and expansion of the medication list to include over-the-counter medications, herbal supplements, medical cannabis, and oxygen. In general, a few commenters suggested that the medication list should be available across encounters and there should not be a distinction between inpatient and ambulatory records. One of these commenters noted that healthcare systems have dropped the distinction and are focusing on a patient medication list. Another commenter stated that the Food and

Drug Administration (FDA) is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. The commenter recommended that we be aware of these efforts and align current and future certification requirements with any future FDA requirements for standards-based identification of prescription drugs.

Response. We thank commenters for their support and have adopted this criterion as proposed. The other comments summarized above are outside the scope of the proposed criterion. We did not propose additional functionality for this criterion, including structured capture in accordance with RxNorm. We also did not propose as part of this criterion to test and certify a Health IT Module's ability to enable a user to record, change, and access a patient's active medication list and medication history across health care settings as this criterion is focused on the ambulatory and inpatient settings in support of the EHR Incentive Programs (please also see our response to comments for the "problem list" certification criterion above). Further, we do not define "medications" for the purpose of testing and certifying a Health IT Module's ability to enable a user to record, change, and access a patient's active medication list and medication history. We thank the commenter for the information related to FDA's work and will take steps to ensure our work aligns with the relevant work of the FDA.

- *Medication Allergy List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(8) (Medication allergy list)

We proposed to adopt a 2015 Edition "medication allergy list" certification criterion that was unchanged as compared to the 2014 Edition "medication allergy list" certification criterion (§ 170.314(a)(7)).

Comments. The majority of commenters supported this criterion as proposed. Multiple commenters recommended adding functionality to support food and environmental allergies as well as other types of allergens, noting that most providers are already recording this information and that such functionality would support patient safety. Some of these same commenters recommended the structured capture of this information in various standards, including RxNorm, UNII, SNOMED CT®, and LOINC®. A

couple of commenters recommended additional functionalities such as including time and date for medication allergies entered, edited, and deleted. In general, a few commenters suggested that the medication allergy list should be available across encounters and there should not be a distinction between inpatient and ambulatory records. One of these commenters noted that healthcare systems have dropped the distinction and are focusing on a patient medication allergy list. Another commenter stated that the FDA is currently working to implement requirements from the Drug Supply Chain Security Act (DSCSA) regarding standards for the interoperable exchange of information for tracing human, finished and/or prescription drugs. The commenter recommended that we be aware of these efforts and align current and future certification requirements with any future FDA requirements for standards-based identification of prescription drugs.

Response. We thank commenters for their support and have adopted this criterion as proposed. The other comments summarized above are outside the scope of the proposed criterion. We did not propose additional functionality for this criterion, including additional allergens and the structured capture of medication allergies. As we noted in the Proposed Rule (80 FR 16820), there are a number of vocabularies and code sets that could support food and environmental allergies as well as medications, but our view is that there is no ready solution for using multiple vocabularies to code allergies that could be adopted for the purposes of certification at this time. We also did not propose as part of this criterion to test and certify a Health IT Module's ability to enable a user to record, change, and access a patient's active medication allergy list and medication allergy history across health care settings as this criterion is focused on the ambulatory and inpatient settings in support of the EHR Incentive Programs (please also see our response to comments for the "problem list" certification criterion above). As noted in our response under the "medication list" certification criterion, we will take steps to ensure our work aligns with the relevant work of the FDA.

- *Clinical Decision Support*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(9) (Clinical decision support)

We proposed to adopt a 2015 Edition "clinical decision support" (CDS) certification criterion that was revised

in comparison to the 2014 Edition "CDS" criterion (§ 170.314(a)(8)). We proposed to require a Health IT Module to follow the updated Infobutton standard (Release 2, June 2014)²⁰ and one of two updated associated IGs: HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013 ("SOA Release 1 IG"),²¹ the updated Infobutton URL-based IG (HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4, June 2014) ("URL-based Release 4 IG").²² We proposed to require certification only to the Infobutton standard (and an associated IG) for identifying diagnostic or therapeutic reference information, as we stated this is the best consensus-based standard available to support the use case. We requested comment on requiring that a Health IT Module be able to request patient-specific education resources identified using Infobutton standards based on a patient's preferred language. We proposed to require that a Health IT Module presented for certification to this criterion be able to record at least one action taken and by whom when a CDS intervention is provided to a user, and that a Health IT Module must generate either a human readable display or human readable report of the responses and actions taken and by whom when a CDS intervention is provided. We clarified that the 2015 Edition CDS certification criterion does not use the terms "automatically" and "trigger" as related to CDS interventions so as to reiterate the intent to encompass all types of CDS interventions without being prescriptive on how the interventions are deployed. We proposed cross-reference corrections to the 2014 Edition CDS criterion.

Infobutton Standard and Related IGs

Comments. A majority of commenters supported the inclusion of the updated Infobutton standard and related IGs. Multiple commenters recommended that there should be more options besides Infobutton for identifying diagnostic or therapeutic reference information. A commenter recommended a requirement for Infobutton to be connected to a reference resource at the end user's choice in cases of inability to use the Infobutton functionality due to

²⁰ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=208.

²¹ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283.

²² http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22.

contractual relationships to reference resources. Multiple commenters voiced a need for materials to be tested and vetted to ensure the accuracy and appropriate literacy level of material, in addition to providers being able to provide educational resources from other sources in case the most appropriate material deemed by the physician cannot be identified or is limited by the health IT.

Response. We thank commenters for their support and have adopted the proposed Infobutton standard and supporting IGs. We clarify for commenters that our certification approach only focuses on capabilities that must be certified to meet this criterion. A health IT developer's product could include other means for identifying diagnostic or therapeutic reference information. Our approach actually reduces burden on health IT developers in that they do not have to have any other means tested and certified. In regard to comments suggesting the certification of the connection to a reference resource and diagnostic or therapeutic reference information obtained, these comments are beyond the scope of our proposal and we have not adopted them.

Preferred Language Request for Comment

Comments. Commenters expressed support for the capability to identify for a user diagnostic and therapeutic reference information based on a patient's preferred language with the use of Infobutton. Commenters stated that this would support reducing racial and ethnic health disparities by improving literacy and addressing language barriers. Some commenters contended that including such as requirement would increase burden for limited value because resources are often not available in other languages with the exception of three or four of the most commonly spoken languages.

Response. We appreciate the comments received in response to this request for comment, including those supporting the inclusion of preferred language. We have, however, not included preferred language functionality in this criterion. While this functionality many support reducing health disparities, we believe that when weighing all proposed policies and the accumulated burden they present, this functionality would not provide as much impact in relation to other proposals such as the structured recording of a patient's preferred language and specific race and ethnicity information under the "demographics" criterion. By not adopting this

functionality, health IT developers will be able to focus more of their efforts on other adopted functionality and requirements, including those that support the interoperability of health IT.

CDS Intervention Response Documentation

Comments. We received mixed comments in response to the proposed additional "recording user response" functionality for this criterion. While many commenters supported the overall goal of interaction checking for quality improvement and patient safety, many commenters stated that current systems already provide a wide range of functionality to enable providers to document decisions concerning CDS interventions. These commenters stated that the proposed "recording user response" is not necessary for certification or for providers to satisfy objectives of the EHR Incentive Programs.

Response. We have not adopted the "recording user response" functionality. This approach is responsive to comments suggesting that this functionality is already included in health IT and is unnecessary to support providers participating in the EHR Incentive Programs. Further, by not adopting this functionality, health IT developers will be able to focus more of their efforts on other adopted functionality and requirements, including those that support the interoperability of health IT.

Clarifying "Automatically" and "Triggered" Regulatory Text

Comments. Commenters expressed agreement with our proposal to not use the terms "automatically" and "trigger" in the 2015 Edition CDS criterion and that CDS interventions should be limited by how they are deployed.

Response. We thank commenters for their support. We have not included these terms in the certification criterion to clarify our intent to encompass all types of CDS interventions without being prescriptive on how the interventions are deployed.

Clinical Decision Support Configuration—Laboratory Tests and Values/Results

Comments. We received a comment seeking clarification on the criterion's reference to laboratory tests and values/results for CDS configuration capabilities related to the incorporation of a transition of care/referral summary. The commenter stated that we should remove reference to laboratory tests and values/results for CDS configuration in relation to the incorporation of a

transition of care/referral summary because the proposed 2015 Edition "clinical information reconciliation and incorporation" criterion does not include reconciling laboratory tests and values/results.

Response. We have removed the references to laboratory tests and values/results from the criterion. The commenter is correct in that the 2015 Edition "clinical information reconciliation and incorporation" criterion does not include reconciling laboratory tests and values/results. Therefore, this data would not necessarily be available for CDS when a patient record is incorporated.

Reordering of Provisions/Regulation Text

We have reordered the provisions of the criterion/regulation text to better align with testing procedures. We have moved the CDS intervention interaction provision to the beginning, followed by the CDS configuration, evidence-based decision support interventions, linked referential CDS, and source attributes. This reordering does not alter the requirements of the criterion in any way.

2014 Edition "Clinical Decision Support" Certification Criterion—Corrections

We received no comments on our proposal to revise the cross-reference in § 170.314(a)(8)(iii)(B)(2) (CDS configuration) to more specifically cross-reference the 2014 "transitions of care" ("ToC") criterion (§ 170.314(b)(1)(iii)(B)). Accordingly, we have adopted this proposed revision.

- *Drug-Formulary and Preferred Drug List Checks*

2015 Edition Health IT Certification Criterion

§ 170.315(a)(10) (Drug-formulary and preferred drug list checks)

In the Proposed Rule, we proposed to adopt a 2015 Edition "drug formulary checks and preferred drug list" certification criterion that was split based on drug formularies and preferred drug lists. We proposed that a Health IT Module must (1) automatically check whether a drug formulary exists for a given patient and medication and (2) receive and incorporate a formulary and benefit file according to the National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard v3.0 ("v3.0"). We proposed that a Health IT Module must automatically check whether a preferred drug list exists for a given patient and medication. For drug formularies and

preferred drug lists, we proposed that a Health IT Module be capable of indicating the last update of a drug formulary or preferred drug list as part of certification to this criterion. We requested comment on more recent versions of the NCPDP Formulary and Benefit Standard to support functionality for receiving and incorporating a formulary and benefit file and sought to understand associated potential development burdens. In addition, we sought comment on a standard for individual-level, real-time formulary benefit checking to address the patient co-pay use case, whether we should offer health IT certification to the standard for this use case, and if this functionality should be a separate criterion from the 2015 Edition “drug formulary and preferred drug list checks” certification criterion.

Comments. Commenters were supportive of splitting the drug-formulary checks functionality from the preferred drug list functionality. A number of commenters stated that the NCPDP Formulary and Benefit Standard provides static, group-level formulary pricing information that does not indicate individual-level, real-time prescription pricing information. A few commenters stated that these static, group-level formularies are not useful for informing discussions with patients about what medications to prescribe because they do not provide information about the patient’s co-pay for a particular drug. Many commenters also suggested that it was not necessary for ONC to offer certification to this functionality because most health IT systems already support NCPDP’s Formulary and Benefit Standard v3.0 due to the Medicare Part D e-prescribing requirements under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Some of these commenters even indicated that they test and certify through Surescripts’ certification program to the standard. In terms of a version of the NCPDP Formulary and Benefit Standard, stakeholders preferred ONC adopt v3.0 rather than any subsequent version to align with the Medicare Part D requirements. Commenters also contended that the industry has widely adopted v3.0 and that newer versions are less stable.

Many commenters stated that there is not an industry-wide accepted standard for real-time individual patient-level formulary checking, but recommended ONC adopt certification to a standard once the industry moves to an agreed-upon standard. A few commenters noted that an NCPDP task group is analyzing use cases to support a real-

time prescription benefit inquiry and is planning to make recommendations to the NCPDP membership on the creation of a new transaction and/or standard or modification of existing transactions or standards.

Response. We appreciate the detailed feedback commenters provided. We have determined that it is most appropriate to not adopt a specific standard for this criterion. We agree with commenters that the NCPDP Formulary and Benefit Standard v3.0 is widely implemented today in support of Medicare Part D requirements and that certification to this standard would add unnecessary burden to health IT developers and providers who are already adhering to the standard.

We believe that certification for individual-level, real-time prescription pricing information will provide the most value to inform provider prescribing decisions and discussions between providers and patients on the most appropriate medication options for the patient. However, at this time, there is no real-time patient-level standard with consensus stakeholder support that would be appropriate for certification. Based on the comments received, we strongly urge the industry to accelerate its work on identifying the need to create a new transaction and/or standard or modify existing transactions or standards for real-time prescription benefit inquiries. We intend to continue our participation in this area and will consider proposing certification functionalities for real-time prescription benefit inquiries in future rulemaking.

With consideration of comments supporting our proposed split of functionality between drug formularies and preferred drug lists, we have adopted a 2015 Edition “drug-formulary and preferred drug list checks” criterion that simply separates drug formulary and preferred drug list functionality, but does *not* require any standards or functionality beyond that included in the 2014 Edition “drug-formulary checks” criterion. As such, this certification criterion is eligible for gap certification.

- *Smoking Status*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(11) (Smoking status)

We proposed to adopt a 2015 Edition “smoking status” certification criterion that was revised in comparison to the 2014 Edition “smoking status” criterion (§ 170.314(a)(11)) and to include the 2015 Edition certification criterion in the 2015 Edition Base EHR definition. To be certified, we proposed that a

Health IT Module must record, change, and access smoking status to any of the September 2014 Release of the U.S. Edition of SNOMED CT® available codes for smoking status, at a minimum. We noted that a Health IT Module certified to certification criteria that reference the Common Clinical Data Set (*i.e.*, the “transitions of care” (“ToC”), “data export” (previously “data portability”), “view, download, and transmit to 3rd party” (VDT), “Consolidated CDA creation performance,” and “application access to the Common Clinical Data Set” certification criteria) would need to be able to code smoking status in only the 8 smoking status codes,²³ which may mean mapping other smoking status codes to the 8 codes. We explained that we expect Health IT developers to work with health care providers to include the appropriate implementation of smoking status codes in a user interface.

Comments. Some commenters stated that health IT should not be required to support the full set of smoking status codes within SNOMED CT® as it would cause unnecessary development burden and potential workflow issues for providers. Multiple commenters also expressed concern with the proper mapping of all of the available smoking status codes within SNOMED CT® to the specified 8 SNOMED CT® smoking codes in the Common Clinical Data Set and used for exchange of patient health information. We also received comments requesting the inclusion of other substances and routes of administration, including the use of chewing tobacco.

Response. We have adopted a “smoking status” certification criterion that does not reference a standard. As stated in the Proposed Rule (80 FR 16870), the capture of a patient’s smoking status has significant value in assisting providers with addressing the number one cause of preventable death and disease in the United States. We have also included this criterion in the Base EHR definition so that this functionality is available to all providers participating in the EHR Incentive Programs. In consideration of the concerns expressed by commenters regarding development burden and the proper mapping of all available smoking status codes within SNOMED CT® to the specified 8 SNOMED CT® for

²³These 8 codes are: current every day smoker, 449868002; current some day smoker, 428041000124106; former smoker, 8517006; never smoker, 266919005; smoker—current status unknown, 77176002; unknown if ever smoked, 266927001; heavy tobacco smoker, 428071000124103; and light tobacco smoker, 428061000124105.

exchange, we believe that the best path forward is the adoption of a “smoking status” criterion that would simply require a Health IT Module to demonstrate that it can enable a user to record, change, and access a patient’s smoking status. In regard to comments suggesting the inclusion of other substances and routes of administration, these comments are beyond the scope of our proposal and we have not adopted them. In sum, this certification criterion is “unchanged” as compared to the 2014 Edition “smoking status” criterion and is eligible for gap certification.

As discussed in more detail under section III.B.3 of this preamble, we have adopted the 8 specified SNOMED CT® smoking codes as part of the Common Clinical Data Set (and for purposes of exchange). This is a continuation of our approach first adopted with the 2014 Edition.

- *Family Health History*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(12) (Family health history)

We proposed to adopt a 2015 Edition “family health history” (FHH) certification criterion that was revised in comparison to the 2014 Edition FHH certification criterion adopted at § 170.314(a)(13). In particular, we proposed to require a Health IT Module to enable a user to record, change, and access a patient’s FHH electronically according to, at a minimum, the concepts or expressions for familial conditions included in the September 2014 Release of the U.S. Edition of SNOMED CT®, which would be a newer baseline version of SNOMED CT® than adopted for the 2014 Edition FHH criterion. The proposed rule’s section III.A.2.d (“Minimum Standards” Code Sets) discussed our adoption of SNOMED CT® as a minimum standards code set and the adoption of the September 2014 Release (U.S. Edition), or potentially a newer version if released before a this final rule, as the baseline for certification to the 2015 Edition.

Comments. Commenters generally supported this certification criterion. Some commenters suggested not adopting this criterion because it does not support a specific meaningful use objective of the proposed EHR Incentive Programs Stage 3. A couple of commenters suggested the recording of FHH is more valuable when it is actually exchanged, with one commenter recommending that we require FFH data be sent using the C–CDA FHH Section with Entries or, minimally, the C–CDA FHH Organizer

Entry. Another commenter suggested that the FHH be stored in a question/answer format (LOINC® for “questions” (observations) and SNOMED CT® for “answers” (observation values)), which would also better support electronic exchange of the information. Some commenters suggested that if this criterion was adopted as proposed that health IT developers should have the ability to attest that their Health IT previously certified to the 2014 Edition FHH criterion meets the newer baseline version of SNOMED CT® for the purposes of testing and certification to this criterion.

Response. We have adopted this certification criterion as proposed, except that we have adopted a newer baseline version SNOMED CT® (September 2015 Release of the U.S. Edition) for the purposes of certification. We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for a more detailed discussion of our adoption of the September 2015 Release of the U.S. Edition of SNOMED CT®. While not supporting a specific meaningful use objective of Stage 3 of the EHR Incentive Programs, this functionality is included in the CEHRT definition. Furthermore, we believe that the FHH functionality is a functionality that should be available to providers for more comprehensive patient care.

We note that our intent is not to limit the use of LOINC® for associated FHH “questions” or the specific SNOMED CT® code that is used to label FHH. Rather, the intent is to capture this information in SNOMED CT® instead of billing terminologies like ICD–10–CM. We also do not intend to prohibit the exchange of this information using the C–CDA 2.1. As we have noted in this and prior rulemakings, certification serves as a baseline. This baseline can be built upon through future regulation or simply through a decision by a health IT developer and/or its customer to include functionality that goes beyond the baseline. As present, we have set the certification baseline for FHH information at recording it in SNOMED CT®.

We agree with commenters that efficient testing and certification processes should be available to Health IT Modules previously certified to the 2014 Edition FHH criterion for certification to this criterion. Accordingly, we will consider such options, such as attestation, in developing the test procedure for this criterion and in issuing guidance to the ONC–AA and ONC–ACBs.

- *Patient-Specific Education Resources*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(13) (Patient-specific education resources)

In the Proposed Rule, we proposed to adopt a 2015 Edition “patient-specific education resources” certification criterion that was revised in comparison to the 2014 Edition “patient-specific education resources” certification criterion (§ 170.314(a)(15)). We proposed that certification would only focus on the use of Infobutton for this certification criterion instead of Infobutton *and* any means other than Infobutton as required by the 2014 Edition criterion. We stated that there is diminished value in continuing to frame the 2015 Edition certification criterion similarly to the 2014 Edition criterion.

We proposed to adopt the updated Infobutton standard (Release 2 and the associated updated IGs (SOA-based IG and URL-based IG)). We also noted that we would not include a requirement that health IT be capable of electronically identifying patient-specific education resources based on “laboratory values/results” because the Infobutton standard cannot fully support this level of data specificity.

We proposed that a Health IT Module be able to request patient-specific education resources based on a patient’s preferred language as this would assist providers in addressing and mitigating certain health disparities. More specifically, we proposed that a Health IT Module must be able to *request* that patient-specific education resources be identified (using Infobutton) in accordance with RFC 5646. We noted that Infobutton only supports a value set of ISO 639–1 for preferred language and, therefore, stated that testing and certification of preferred language for this certification criterion would not go beyond the value set of ISO 639–1. We further noted testing and certification would focus only on the ability of a Health IT Module to make a request using a preferred language and Infobutton because the language of patient education resources returned through Infobutton is dependent on what the source can support.

Comments. Multiple commenters supported the inclusion of the updated Infobutton standard and supporting IGs. A few commenters expressed concern about limiting certification to only Infobutton and suggested there are other viable options for requesting patient-specific education resources. A commenter requested clarification as to whether providers must only use certified health IT for requesting patient-specific education resources for

the purposes of participating in the EHR Incentive Programs.

Response. We thank commenters for their support and have adopted the proposed Infobutton standard and supporting IGs. We continue to believe that the Infobutton capability is important to be available to providers to have and use to identify patient-specific education resources. We clarify for commenters that our certification approach only focuses on capabilities that must be certified to meet this criterion. A health IT developer's product could include other means for requesting patient-specific education resources. Our approach actually reduces burden on health IT developers in that they do not have to have any other means tested and certified. For questions related to the EHR Incentive Programs, we refer readers to CMS and the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

Comments. We received a few comments supporting our approach for "laboratory values/results."

Response. We have not included "laboratory values/results" as patient data that must be used to identify patient-specific education resources.

Comments. Commenters expressed strong support for the capability to request patient-specific education materials based on a patient's preferred language with the use of Infobutton. Commenters stated that this would support reducing racial and ethnic health disparities by improving literacy and addressing language barriers. Commenters also expressed a need for materials to be tested and vetted to ensure the accuracy and appropriate literacy level of the materials. Some commenters contended that this requirement would increase burden for limited value because educational resources are often not available in other languages with the exception of three or four of the most commonly spoken languages.

Response. We thank commenters for their support and feedback. With consideration of the mixed feedback, we have determined to designate the use of preferred language as an optional provision within this criterion. As optional, health IT developers have flexibility to pursue certification if they deem it advantageous. With our new open data CHPL (see section IV.D.3 of this preamble), information on whether a Health IT Module was certified to this functionality would be readily available for consumers.

- *Implantable Device List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(14) (Implantable device list)

In the Proposed Rule, we proposed to adopt a new 2015 Edition certification criterion focused on the ability of health IT to exchange, record, and allow a user to access a list of Unique Device Identifiers (UDIs)²⁴ associated with a patient's implantable devices. Health IT certified to the proposed criterion would be able to "parse" a UDI into its constituent components (or "identifiers") and make those accessible to the user. Separately, the health IT would be able to retrieve and provide a user with access to, if available, the optional "Device Description" attribute associated with a UDI in the FDA's Global Unique Device Identification Database (GUDID). Further, to facilitate the exchange of UDIs and increase their availability and reliability in certified health IT, we proposed to include the proposed 2015 Edition implantable device list certification criterion in the 2015 Edition Base EHR definition and to include a patient's UDIs as data within the CCDS definition for certification to the 2015 Edition. We also proposed to modify § 170.102 to include new definitions for "Device Identifier," "Implantable Device," "Global Unique Device Identification Database (GUDID)," "Production Identifier," and "Unique Device Identifier."

We explained that the purpose of the proposed implantable device list certification criterion was to enable the baseline functionality necessary to support the exchange and use of UDIs in certified health IT. The need to exchange and have access to this information wherever patients seek care is broadly relevant to all clinical users of health IT, regardless of setting or specialty, so that they may know what devices their patients are using (or have used) and thereby prevent device-related adverse events and deliver safe and effective care.²⁵ This need is most

²⁴ 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. 21 CFR 801.3. See also <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>.

²⁵ In addition, as UDIs become ubiquitous, UDI capabilities in health IT will support other

acute for implantable devices, which by their nature are difficult to detect and identify in the absence of reliable clinical documentation.

We acknowledged in the Proposed Rule that fully implementing UDIs in health IT will take time and require addressing a number of challenges. Nevertheless, we noted that substantial progress has been made. In particular, we summarized the FDA's regulatory activities and timeline for implementing the Unique Device Identification System and extensive work by public and private sector stakeholders to advance standards and specifications in support of UDI use cases. On the basis of these developments and our own ongoing consideration of these and other issues,²⁶ we recognized that while "the path to full implementation is complex, there are relatively straightforward steps" that we could take now to support the electronic exchange and use of UDIs, beginning with UDIs for implantable devices. Our proposed certification criterion focused narrowly on implementing these first steps.

In light of the foregoing and with the revisions discussed below in our analysis of the comments on this proposal, we have finalized a 2015 Edition "implantable device list" certification criterion. We have also finalized our proposals to include this certification criterion in the 2015 Base EHR definition and to include a patient's UDIs as data within the 2015 Common Clinical Data Set definition. Discussion of those proposals can be found elsewhere in this final rule.

Comments. Most commenters agreed with the central premise of our proposal, that enabling the exchange and use of UDIs in certified health IT is a key initial step towards realizing the substantial patient safety, public health, and other benefits of UDIs and the Unique Device Identification System. Many commenters strongly supported the proposed criterion, including its focus on implantable devices. Commenters stated that the ability to exchange and access identifying information about patients' implantable devices wherever patients seek care would enable clinicians to prevent device-related medical errors and improve the quality of care provided to patients. Commenters also stated that the need to access accurate information

important benefits, including better surveillance and evaluation of device performance and more effective preventative and corrective action in response to device recalls.

²⁶ As further context for our proposal, we described our previous consideration of these and other issues related to UDI adoption in a previous rulemaking. 79 FR 10894.

about patients' implantable devices is broadly applicable to primary care physicians, specialists, and other providers to support care coordination and ensure that providers have a complete medical history of their patients.

Many commenters supported the proposed criterion in full and recommended that we finalize it without any substantial revision. A significant number of commenters also urged to expand the scope of this criterion to include additional UDI-related capabilities. In contrast, a significant number of commenters stated that we should not finalize this criterion or should make all or part of it an optional certification criterion for the 2015 Edition. Commenters also offered a variety of suggested revisions and refinements with respect to the capabilities we proposed.

Response. We have adopted this certification criterion substantially as proposed, subject to certain revisions and clarifications discussed further below in response to the comments we received. We thank commenters for their detailed and thoughtful feedback on our proposal. We reiterate that this certification criterion represents a *first step* towards enabling the widespread exchange and use of UDIs and related capabilities in certified health IT, beginning with implantable devices. Because we recognize that fully implementing UDIs in health IT will take time and require addressing a number of challenges, the certification criterion focuses narrowly on baseline health IT capabilities that developers can feasibly implement today. These capabilities will provide the foundation for broader adoption and more advanced capabilities and use cases. We believe that this approach minimizes the potential burden while maximizing the impact of this criterion for all stakeholders.

Comments. A significant number of commenters who supported our proposed implantable device list certification criterion also recommended that we adopt additional UDI-related capabilities, either as part of this criterion (which we proposed to reference in the 2015 Edition Base EHR definition) or as a separate, optional certification criterion. Many commenters urged us to include requirements for Automatic Identification and Data Capture (AIDC) of UDIs. Commenters stated that such a requirement would facilitate the accurate and efficient capture of UDIs and align this criterion with the UDI final rule, which requires UDIs to support one or more forms of AIDC.

Some commenters also stated that if we did not require—or at least provide the option for—AIDC, users may be forced to manually enter UDIs. They stated that this could discourage them from capturing UDIs, which could lead to incomplete or inaccurate information about patients' implantable devices. Separate from AIDC, several commenters suggested that we adopt other UDI-related capabilities, such as the ability to generate lists of patients with a particular device; to generate notifications to patients in the event of a device recall; and to record and track information about non-implantable devices and medical and surgical supplies that are not regulated as a device.

Response. We have not adopted any AIDC requirements for UDIs as part of this final rule. While we unequivocally agree with commenters that UDIs should be captured using AIDC and should rarely if ever be manually entered; and while for this reason we strongly urge health IT developers and health care organizations to implement AIDC capabilities in all settings and systems in which UDIs may be captured; yet for the reasons elaborated below, we believe at this time that certification is neither an effective nor appropriate means to further these policies. As we explained in the Proposed Rule, this criterion is not intended to provide the capability to enter or "capture" UDIs for implantable device, such as during the course of a procedure. The reason for this is that the capture of UDIs currently occurs in a wide variety of "upstream" IT systems and settings that are beyond the scope of the current ONC Health IT Certification Program. Rather than ineffectually trying to address these "upstream" use cases, we have chosen to focus this certification criterion on the baseline functionality necessary to ensure that, once recorded in a patient's electronic health record, UDIs can be exchanged among "downstream" health IT systems (the overwhelming majority of which we do certify) and accessed by clinicians wherever patients seek care.

Some commenters understood our rationale for not requiring AIDC capabilities for all certified health IT and instead recommended we adopt a separate optional AIDC certification criterion that could be leveraged by certified health IT designed for operating rooms and other surgical settings in which devices are implanted or removed. While we appreciate the suggestion, such a certification criterion would be applicable to only a small subset of certified health IT, which in turn represents only a small subset of IT

systems used to capture UDIs for implantable devices. Moreover, prescribing specific AIDC requirements for certified health IT may also be unnecessary. Given the obvious convenience, accuracy, and other advantages of AIDC, we anticipate that users of certified health IT designed for surgical settings will expect developers to include AIDC capabilities as a necessary complement to the baseline implantable device list functionality required by this criterion. Allowing developers and their customers to design and implement the most appropriate AIDC solutions for their individual needs is consistent with FDA's policy of permitting flexibility in the use of these technologies and avoids imposing unnecessary requirements and costs on developers, providers, and our testing and certification bodies.

Contrary to the suggestions of some commenters, our decision not to adopt a particular AIDC requirement for implantable devices does not mean that users of certified health IT systems will be forced to manually record UDIs. Again, for the reasons we have stated, this criterion has no bearing on how UDIs are entered or captured in upstream IT systems during a procedure or operation. It is tailored solely to bringing and providing capabilities for UDIs to downstream EHR and health IT systems used in physicians' offices, hospitals, and other places where patients with implantable devices seek care.

Similarly, at this time we believe that it would be premature to include other capabilities suggested by commenters. Some of those capabilities—such as the ability to record information about non-implantable devices—are beyond the scope of the proposal. For other capabilities, greater adoption and use of UDIs in certified health IT is needed before the capabilities will be useful to most health IT users. For example, we recognize that being able to generate a list of patients with a particular device will be necessary to respond to device recalls and analyze device performance and other characteristics. But those benefits cannot materialize until UDIs are more broadly and more readily accessible through interoperable health IT and health information exchange. Likewise, achieving these benefits will first require implementing other baseline functionality included in this criterion, such as the ability to retrieve key device attributes from the GUDID. We think that focusing the requirements of this criterion—and thus the efforts of developers and users of certified health IT—on these essential baseline functionalities is the quickest path to

the adoption of UDIs in health IT and thus to creating demand and opportunities for the more advanced capabilities commenters envision.

Comments. Some commenters requested clarification as to what constitutes an “implantable device” for purposes of this certification criterion.

Response. We have adopted new definitions in § 172.102 for “Implantable Device” and several other terms by cross-referencing the definitions for those terms already provided at 21 CFR 801.3. We believe adopting these definitions in our final rule will prevent any interpretative ambiguity and ensure that each phrase’s specific meaning reflects the same meaning given to it in the Unique Device Identification System final rule. For further discussion of these new definitions, we refer readers to section III.B.4 of this preamble.

Comment. A commenter recommended that we use the term “identifier” instead of the term “data element” to refer to the following identifying information that composes the Production Identifier portion of a UDI:

- The lot or batch 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; and
- for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

To avoid confusion and align our terminology with the UDI final rule, the commenter recommended we refer to these “data elements” as “identifiers” or “production identifiers.”

Response. We agree that our use of the term “data elements” was imprecise and could lead to unnecessary confusion. Accordingly, we have revised our terminology as follows to align more closely with the UDI final rule.

In our proposal, we used the term “data elements” to describe two distinct types of information associated with UDIs. First, we said that a Health IT Module certified to our proposed criterion would have to be able to parse certain “data elements from a UDI” and make these accessible to a user. 80 FR 16825. In that context, we were referring to what the UDI final rule describes as the “production identifiers that appear on the label of the device.” 21 CFR 830.310(b)(1). These are the identifiers listed above that compose and are required to be included in the Production Identifier when required to be included on the label of a device. 21

CFR 801.3. Because these identifiers are part of the UDI, health IT should be able to parse these identifiers from the UDI using the issuing agency’s specifications. There is no need to query an external database or source, such as the GUDID.

Second, we also used the same term, “data element,” to refer to certain information not included in the UDI itself but that is associated with the UDI and can be retrieved using the GUDID. Specifically, we proposed that health IT be able to retrieve and make accessible the optional “Device Description” attribute associated with the Device Identifier portion of the UDI (assuming the attribute has been populated in the GUDID).

To distinguish these separate concepts and for consistency with the UDI final rule, this preamble and the corresponding regulation at § 170.315(a)(14) use the terms “identifier” and “attribute” to refer to the two distinct types of information described above.

Comments. Many commenters, including some health IT developers, supported the requirement to parse a UDI and allow a user to access the identifiers that compose the UDI. Other commenters stated that requiring this functionality would be burdensome because UDIs may be issued by different issuing agencies and in different formats. Some commenters suggested we withdraw this proposed requirement until a canonical format is established to harmonize and streamline the process of parsing UDIs issued by different FDA-accredited issuing agencies and in different formats.

A number of commenters pointed out that we had omitted from this requirement the Distinct Identification Code required by 21 CFR 1271.290(c), which is one of the five identifiers that make up the Production Identifier and applies to human cells, tissues, or cellular and tissue-based products (HCT/P) regulated as a device, including certain kinds of implantable devices (e.g., skin grafts and bone matrixes). To ensure the exchange of UDIs for all implantable devices and to avoid misalignment with the UDI final rule, we were urged to include the Distinct Identification Code among the identifiers that technology must be able to parse and make accessible to a user under this criterion.

Response. The requirement to parse a UDI is reasonable despite the existence of multiple issuing agencies and formats. We disagree that this requirement is burdensome and note that it was supported by several health IT developers. This criterion would

require health IT to be able to parse UDIs issued by FDA-accredited issuing agencies. There are currently three FDA-accredited issuing agencies (GS1, HIBCC, and ICCBBA)²⁷ and each issuing agency has only one approved UDI format. All three formats are unique and can thus be readily distinguished by health IT and parsed according to the correct format. The formats themselves are described in detail in a single five-page reference document available on the FDA Web site.²⁸ Each format has been approved by the FDA, and no changes can be made unless the FDA similarly approves of the changes prior to implementation.

We disagree that the requirement to parse a UDI should be postponed until the emergence of a single canonical UDI format. It is unclear at this time when or if such a canonical format will be developed and whether it would support the functionality we are requiring. It is also unclear whether implementing a canonical format would reduce or increase the overall technical complexity and burden of implementing these capabilities for multiple UDI formats. Meanwhile, postponing these capabilities would frustrate the purpose of this certification criterion. Without the ability to parse a UDI, health IT would be unable to provide users with useful information identifying and safety-related information about a device, such as the device’s expiration date (which will be parsed from the Production Identifier) or a description of the device (which will be retrieved by parsing and looking up the Device Identifier in the GUDID).

The omission of “Distinct Identification Code required by 21 CFR 1271.290(c)” among the identifiers that health IT must be able to parse was an oversight, and we thank commenters for bringing it to our attention. We agree that to avoid misalignment with the UDI final rule, health IT should be required to parse this identifier and make it accessible in the same manner required for the other identifiers that compose the Production Identifier, as referenced in the Proposed Rule. We therefore

²⁷ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm>.

²⁸ FDA, *UDI Formats by FDA-Accredited Issuing Agency* (May 7, 2014), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.doc>. The reference document is one of two technical documents made available by the FDA to assist labelers and other persons to comply with the GUDID Guidance. See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm>.

include it with those identifiers at § 170.315(a)(14)(ii). For similar alignment and consistency, we also include the Production Identifier itself in the list of identifiers at § 170.315(a)(14)(ii).

Comments. Several commenters objected to the proposed requirement that health IT be able to query a UDI against the GUDID and retrieve the associated “Device Description” attribute (when that attribute has been populated and is available). Some commenters stated that it was unreasonable to expect developers to implement GUDID capabilities before all of the planned GUDID functionality is available. At the time of the Proposed Rule, the GUDID was available as a downloadable file, which was and continues to be updated daily. A web interface and web services were also planned but had not yet been implemented. Although we explained that the daily downloadable version of GUDID could be used to satisfy the proposed criterion, some commenters insisted that we should not require any GUDID retrieval capabilities until web services are in place to enable GUDID attributes to be easily retrieved “on demand.” Several commenters requested that we clarify FDA’s timeline for implementing web services.

Response. FDA has partnered with the National Library of Medicine (NLM) to implement the GUDID. The GUDID is now available via a web interface called AccessGUDID.²⁹ In addition, FDA has confirmed that web services will be available via the AccessGUDID website by October 31, 2015. These web services are being implemented to support health IT developers to meet this implantable device list certification criterion. For any valid UDI, the web services will return the following GUDID attributes:

- “GMDN PT Name”;
- “Brand Name”;
- “Version or Model”;
- “Company Name”;
- “What MRI safety information does the labeling contain?”; and
- “Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).”

In addition to these GUDID attributes, and for the convenience of health IT developers, the web services will also return the “SNOMED CT® Identifier” and the “SNOMED CT® Description” mapped to the GMDN code set.³⁰

As commenters acknowledged, including many who objected to this requirement, the availability of dedicated web services for retrieving the attributes associated with a UDI from the GUDID will significantly streamline and reduce the costs of including this functionality in certified health IT. We take the commenters at their word and believe that the availability of these dedicated web services—which will be specifically designed for health IT developers and aligned with this certification criterion—will substantially mitigate the concerns raised by developers and other commenters regarding the potential burden or technical challenges of implementing GUDID functionality.

Comments. Several commenters were puzzled by our proposal to require retrieval only of the “Device Description” attribute. They pointed out that submission of this attribute to the GUDID is optional and is not standardized. The proposed requirement would therefore be unlikely to serve our goal of providing clinicians and patients with accurate and accessible information about implantable devices. Some commenters suggested that the “Global Medical Device Nomenclature (GMDN) PT Name” attribute would better suit our purpose and noted that this attribute, unlike “Device Description,” is a required attribute and a recognized international standard for medical device nomenclature.

Several commenters also urged us to require retrieval of additional GUDID attributes. Several commenters noted that certain safety-related attributes—specifically “What MRI safety information does the labeling contain?” and “Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)” —are required to be submitted to the GUDID, are already available, and would significantly further the patient safety aims outlined in our proposal. Along the same lines, other commenters identified additional GUDID attributes that would enable identification of the manufacturer or labeler (i.e., company name), brand, and specific version or model of a device.

Response. We believed that retrieving the “Device Description” attribute would be a good starting point for GUDID functionality under this criterion and would make the implantable device list more useful to

clinicians by displaying the familiar name of each device in the list next to the device’s UDI. Based on the comments, we accept that the “GMDN PT Name” attribute is more suitable for our purposes because it is a recognized international standard for medical devices and, unlike the “Device Description” attribute, is required and therefore much more likely to in fact be populated in the GUDID. We are therefore revising § 170.315(a)(14)(iii) to require the “GMDN PT Name” attribute instead of “Device Description.” Relatedly, we have also revised § 170.315(a)(14)(iii) to permit health IT developers who meet this requirement using the GUDID web services to do so in either of two ways. They may either retrieve the “GMDN PT Name” attribute or, alternatively, the “SNOMED CT® Description” associated with a UDI. Pursuant to a cooperative agreement between the relevant standards developing organizations, the SNOMED CT® code set is being mapped to GMDN PT and thus the description of a device will be identical under both terminologies. However, we expect that many developers will prefer to use the SNOMED CT® code set because they already do so and because they can retrieve the computable “SNOMED CT® Identifier,” which will also be available via the web services and will enable developers to more easily deploy CDS and other functionality for implantable devices. Thus allowing developers the flexibility to retrieve the “SNOMED CT® Description” in lieu of the identical mapped “GMDN PT Name” attribute will avoid requiring them to support multiple and duplicative code sets for medical devices and may also encourage them to incorporate more advanced capabilities for implantable devices, consistent with the goals of this criterion.

As discussed above, the GUDID web interface is now available via the NLM AccessGUDID website, which will soon be augmented with dedicated web services designed to support health IT certified to this criterion. With this increased readiness of the GUDID, health IT should be able to retrieve additional GUDID attributes with little additional effort. Therefore, we are also including the following attributes among those that must be retrieved and made accessible to users of health IT certified to this criterion:

- “Brand Name”;
- “Version or Model”;
- “Company Name”;
- “What MRI safety information does the labeling contain?”; and

²⁹ See <http://accessgudid.nlm.nih.gov/>. A list of APIs currently in development is available at <http://accessgudid.nlm.nih.gov/docs>.

³⁰ Under a Cooperative Agreement between the Global Medical Device Nomenclature Agency and

the International Health Terminology Standards Development Organization (IHTSDO), GMDN will be used as the basis for the medical device component of SNOMED CT®. See <http://www.ihtsdo.org/resource/resource/84>.

• “Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).”³¹

For the reasons that commenters identified, these particular attributes will further the core goals of this criterion by significantly enhancing the ability of clinicians to identify and access important safety-related information about their patients’ implantable devices.

Comment. A commenter noted that this criterion would require health IT to retrieve UDI attributes exclusively from the GUDID. The commenter recommended we consult with FDA to ensure that the GUDID will be able to support the potentially large volume of requests that could result from this requirement.

Response. As discussed above, FDA and NLM are implementing web services specifically to support health IT developers to meet this implantable device list certification criterion. FDA has signed an interagency agreement with NLM to provide public access to AccessGUDID, including web services. NLM has experience with large volume requests and will be able to meet any demands generated by developers and users as a result of this criterion.

Comments. Some commenters noted that UDI attributes are not exclusive to the GUDID and are commonly stored in providers’ enterprise resource planning systems (ERPS), materials management information systems (MMIS), and other “systems of record.” Thus, instead of requiring health IT to always retrieve the UDI attributes from the GUDID, it was suggested that we permit attributes to be retrieved from these and other appropriate sources, thereby giving providers and developers (who may have different database and technical infrastructures) the flexibility to select the most appropriate source of this information.

Response. As we stated in the Proposed Rule, the requirement to retrieve attributes from the GUDID can be accomplished using the GUDID’s web interface, web services, downloadable module, or any other method of retrieval permitted under FDA’s GUDID guidance. Thus GUDID attributes could be retrieved from a local system, provided the information in that system is up to date and is based upon the data downloaded from the GUDID. That said, we encourage the use of the

AccessGUDID web services, which as discussed above are being designed specifically to support health IT developers to meet this implantable device list certification criterion.

Comments. Commenters overwhelmingly supported our proposal to require that health IT enable a user to change a UDI in a patient’s implantable device list and, in appropriate circumstances, “delete” erroneous, duplicative, or outdated information about a patient’s implantable devices. However, several commenters took issue with our use of the term “delete,” which could imply that a user should be able to completely remove a UDI and associated information from a patient’s implantable device list and from the patient’s electronic health record altogether. Commenters stated that information about a patient’s implantable devices should be retained for historical accuracy and context. One commenter noted that allowing users to delete this information could violate record retention laws. Several commenters suggested that we clarify that a user should be able to “flag” or otherwise annotate a UDI as no longer active while still retaining the UDI and associated information.

The comments on this aspect of our proposal suggest some confusion surrounding the concept of an “implantable device list” contemplated in the Proposed Rule. Different commenters used the term “implantable device list” to refer to at least three distinct constructs: (1) The list of UDIs that would be recorded and exchanged as structured data; (2) the presumably more detailed list of information about a patient’s implantable devices that would subsist separately and locally in EHR systems; and (3) the list of UDIs and other information that would be formatted and presented to users of an EHR system. Some commenters recognized this ambiguity and asked us to be more precise. But several commenters oscillated between these different constructs and imputed them to different parts of our proposal, depending on the context. As a result, some of these commenters perceived in our proposal elements that had not been proposed, such as the ability to enable a user to manually record a UDI or to exchange certain kinds of information about implantable devices.

Response. We appreciate commenters’ feedback on this aspect of our proposal. We agree that a user should not be able to permanently “delete” UDIs recorded for a patient. Therefore, we are adopting the approach suggested by most commenters that would allow a user to

change the status of a UDI but would require that UDI itself not be deleted and still be accessible to a user. Specifically, health IT certified to this criterion must enable a user to change the status of a UDI recorded for a patient to indicate that the UDI is inactive. We also expect that developers will implement this functionality in a manner that allows users to indicate the reason that the UDI’s status was changed to inactive. Consistent with the policy that UDIs should not be deleted from the implantable device list or from a patient’s electronic health record, a UDI that has been designated inactive must still be accessible to the user so that users can access information about the device, even if it was explanted or recorded in error. We expect that both the status and other appropriate metadata will be recorded in a manner consistent with the C–CDA, where applicable, and will be exchanged with the UDI according to that standard.

As noted above, the comments on this aspect of our proposal suggest the need for greater precision regarding the concept of an “implantable device list.” In this final rule, we use the term “implantable device list” to refer to the visible list that is displayed to the user of health IT certified to this criterion and that must show, at a minimum: (1) A patient’s active UDIs, meaning all UDIs recorded for the patient that have not been designated inactive; (2) the corresponding description of each UDI in the list (which, as discussed above, may be either the GUDID attribute “GMDN PT Name” or the “SNOMED CT® Description” mapped to that attribute); and (3) if one or more inactive UDIs are not included in the list, a method of accessing those UDIs and their associated information from within the list. The implantable device list may but need not also include the identifiers and attributes associated with each UDI that the health IT must be able to retrieve and make accessible to a user. If the implantable device list does not contain these identifiers and attributes, then the health IT would need to enable a user to access them (for example, by presenting them when a user clicks on an item in the implantable device list). Similarly, the implantable device list may but need not include inactive UDIs, so long as these UDIs are accessible from within the list. For example, the implantable device list could display only active UDIs so long as it also contained a link or other obvious way for a user to access all other UDIs recorded for the patient.

The discussion above should make clear that we are using the term “implantable device list” to refer to the

³¹ Current GUDID attributes are derived from the UDI final rule and are specified in the FDA GUDID Data Elements Reference Table (May 1, 2015). <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUIDatabaseGUDID/UCM396592.xls>.

UDIs and other information that must be presented and made accessible to a user in the manner described above. This information is distinct from the information not visible to a user that must be recorded and exchanged by health IT certified to this criterion. That information is not an “implantable device list” but rather a list of UDIs recorded for a patient and the associated metadata that must be recorded and exchanged in accordance with the requirements of the CCDS definition, the 2015 Base EHR definition, and the C-CDA standard. We discuss this data separately below in response to comments regarding the exchange of contextual information about a patient’s implantable devices. To avoid any ambiguity or misinterpretation, we have structured § 170.315(a)(14) to more precisely codify the concepts explained above.

Comments. In the Proposed Rule, we stated that this certification criterion would not require health IT to be able to exchange or use contextual information about a device (such as a procedure note). We requested comment on whether we had overlooked the need for or feasibility of requiring this functionality. Many of the comments we received emphasized the importance of recording and exchanging contextual information about implantable devices. Some commenters expressed concerns that exchanging UDIs without their proper context could lead to interoperability, patient safety, or other implementation challenges. Some commenters also urged us to specify precisely how contextual information associated with an implantable device should be recorded and exchanged among health IT certified to this criterion. These commenters did not identify any specific standards or implementation specifications. Several other commenters explained that current standards and implementation guides do not specify a consistent approach to documenting this information.

Response. We recognize the importance of contextual information about patients’ implantable devices. As described elsewhere in this rule, we have included the Unique Device Identifier in the CCDS definition with the intent of capturing and sharing UDIs associated with implantable devices in both internal EHR records as well as exchangeable documents. We clarify that, where the UDI is present and represents an Implantable Device, the UDI should be sent in accordance with the C-CDA, which specifies its inclusion in the Procedure Activity section of exchangeable documents. We

also expected that appropriate associated metadata, such as the date and site of the implant, will be included with the UDI where available as specified in the standard.³²

Beyond these basic parameters, we believe it is premature to prescribe the exact content and form of contextual information associated with UDIs. The comments confirm our observation in the Proposed Rule that additional standards and use cases will be needed to support this functionality.

Comments. Some commenters insisted that the proposed criterion lacked relevance to the majority of providers who do not practice in surgical or certain kinds of inpatient settings. For this reason, they suggested that we remove some or all of the criterion from the 2015 Base EHR definition or from the final rule.

Some commenters who otherwise supported our proposal felt that we should not include this certification criterion in the Base EHR or should make some of the proposed requirements optional in the 2015 Edition. Similarly, some commenters objected to the inclusion of a patient’s Unique Device Identifiers in the CCDS definition. Some of these commenters objected in principle to including any requirements that are not correlated with a meaningful use objective or measure, while others objected on the basis that this certification criterion would be unduly costly and burdensome for developers and could place significant and unnecessary burdens on providers.

Several commenters claimed that this criterion was not ripe and there were a lack of available standards for certain aspects of our proposal. Commenters also cited potential implementation challenges, especially the fact that UDIs and other information about implantable devices are often captured in IT systems that are not part of certified health IT. Because bridging these systems will be challenging without more mature standards or customized interfaces, the information in these systems may not be recorded in certified health IT.

Response. Again, we reiterate that this criterion is not aimed at surgical specialties, settings, or systems. It is aimed at delivering information to all clinicians so that they can know what

³² The UDI for implantable devices is encoded and exchanged in the Procedure Activity Procedure (V2) section of C-CDA, which contains a Product Instance template that can accommodate the UDI the implantable device, the implant date, and the target site. Although not required by the standard, this information should be sent if available, as with all of the CCDS content.

devices their patients have and use that information to deliver safer and more effective care. We take seriously the concerns raised by some commenters regarding the potential costs and burdens of the proposed criterion. We have addressed those concerns above in our responses to comments on the specific aspects of our proposal to which those concerns pertain. We note that for many of these aspects, health IT developers often contradicted one another as to the relative costs and difficulty of implementing the UDI-related capabilities we proposed. As just one illustration, several EHR developers stated that the requirement that health IT be able to parse a UDI was infeasible or would be unduly burdensome. In contradistinction, a different EHR developer objected to other aspects of the proposal but specifically endorsed the capability to parse UDIs; and yet another EHR developer supported all of the capabilities we proposed. In short, health IT developers’ comments regarding cost and burden often pointed in different directions, which suggests that many of their concerns are idiosyncratic to particular developers, not generalizable to all developers or the health IT industry. We submit that competition in the marketplace is the more appropriate vehicle for mediating such differences, not our regulations.³³

Because all providers should have access to information about their patients’ implantable devices, we are including a patient’s Unique Device Identifiers in the CCDS definition. To ensure that all certified health IT has the basic ability to exchange, record, and make this information available, we are including this certification criterion in the 2015 Base EHR definition. These definitions are not limited to the EHR Incentive Programs and must support other programs as well as the broader needs of health IT users throughout the health care system. We refer commenters to our discussion of these definitions elsewhere in this final rule. We decline to postpone this criterion until the Unique Device Identification System is fully implemented for all devices and across the entire medical device industry, or until additional standards are fully developed and harmonized for additional use cases. While this work is ongoing, UDIs are required to be available for all implantable devices by September 2015. Similarly, standards already exist for recording and exchanging UDIs for

³³ In this connection we refer readers to the discussion of the new transparency and disclosure requirements for health IT developers finalized elsewhere in this rule.

implantable devices as structured data in patients' electronic health records. These standards have been refined since the last time we proposed to adopt a certification criterion for implantable devices. And, as noted above, the GUDID is now available via the NLM's AccessGUDID website and will support web services for this certification criterion. While full implementation of the Unique Device Identification System will take several years, and while the development of standards is an ongoing process, UDIs for implantable devices can begin to be incorporated in health IT and will support and help accelerate these other efforts.

Commenters concerns regarding potential "upstream" implementation challenges are valid, but we have addressed those concerns by focusing this certification criterion only on the baseline functionality necessary to ensure that, once recorded in a patient's electronic health record, UDIs can be exchanged among certified health IT and accessed by users of certified health IT wherever the patient seeks care.

• *Social, Psychological, and Behavioral Data*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(15) (Social, psychological, and behavioral data)

We proposed to adopt a new 2015 Edition "social, psychological, and behavioral data" certification criterion that would require a Health IT Module to be capable of enabling a user to record, change, and access a patient's social, psychological, and behavioral data based on SNOMED CT® and LOINC® codes, including sexual orientation and gender identity and the ability to record a patient's decision not to provide information. As the Proposed Rule explained, the proposed certification criterion is designed to advance the collection and use of such patient data, to transform health delivery, to reduce health disparities, and to achieve the overarching goals of the National Quality Strategy. We proposed that social, psychological, and behavioral data be coded in accordance with, at a minimum, version 2.50 of LOINC®, and we explained that LOINC® codes will be established in a newer version of LOINC® for the question-answer sets that do not currently have a LOINC® code in place, prior to the publication of the final rule. We proposed that sexual orientation be coded in accordance with, at a minimum, the September 2014 Release of the U.S. Edition of SNOMED CT® and HL7 Version 3 that gender identity be

coded in accordance with, at a minimum, the September 2014 Release of the U.S. Edition of SNOMED CT® and HL7 Version 3, as enumerated in tables in the Proposed Rule. We sought comment on inclusion of the appropriate social, psychological, and behavioral data measures, on standardized questions for collection of sexual orientation and gender identity data, on a minimum number of data measures for certification, on combining and separating the measures in certification criteria, and on inclusion of additional data and available standards.

Comments. Many commenters were in support of our proposal to include a new certification criterion for the capture of social, psychological, and behavioral data. Commenters recommended that we consider including security and privacy safeguards for this information and additional measures relevant to other settings (e.g., oral health measures, behavioral health diagnosis history, expansion of violence measures, and expansion of measure applicability to parents of pediatric patients). Commenters also recommended that we verify proposed LOINC® codes that were listed as pending in the Proposed Rule.

Some commenters were against certification for this data. These commenters cited lack of uses cases for the data, overburdening providers with data collection, and lack of maturity of data standards. A few commenters were not supportive of additional certification for criteria that are not proposed to specifically support Stage 3 of the EHR Incentive Programs.

Response. We thank commenters for their feedback. We have adopted a 2015 Edition "social, psychological, and behavioral data" certification criterion that is described in more detail below. As stated in Proposed Rule (80 FR 16826), we continue to believe that offering certification to enable a user to record, change, and access a patient's social, psychological, and behavioral data will assist a wide array of stakeholders in better understanding how this data may adversely affect health and ultimately lead to better outcomes for patients. We also believe that this data has use cases beyond the EHR Incentive Programs, including supporting the Precision Medicine Initiative³⁴ and delivery system reform. In addition, the Federal Health IT Strategic Plan aims to enhance routine medical care through the incorporation of more information into the health care process for care coordination and a

more complete view of health, including social supports and community resources.³⁵ We believe the collection of the information in certified Health IT Modules through this criterion can better inform links to social supports and community resources.

In regard to comments expressing privacy and security concerns, we first note that the functionality in this criterion is focused on capture and not privacy and security. Second, we have established a privacy and security certification framework for all Health IT Modules that are certified to the 2015 Edition (please see section IV.C.1 of this preamble). Third, we recommend that institutions develop and maintain policies for the collection and dissemination of this data that is consistent with applicable federal and state laws.

We appreciate comments on additional data to consider for inclusion in this criterion. We have, however, determined that the proposed list presents an appropriate first step for the standardized collection of social, behavioral, and psychological data. We note, based on feedback from commenters, we have included the capture of sexual orientation and gender identity (SO/GI) data in the 2015 Edition "demographics" certification criterion. We will continue to consider whether this list should be expanded through future rulemaking.

We have verified the LOINC® codes that were proposed and obtained the codes for those listed as pending in the Proposed Rule, and have provided the proper codes and answer list IDs for all eight domains we are adopting in this criterion (please refer to § 170.207(p)) for the full list of LOINC® codes).

Comments. There were mixed comments on whether we should adopt all proposed domains in one criterion or adopt a separate criterion for each proposed domain. We also received mixed feedback on whether certification would be to all domains, a select number, or at least one. Commenters in favor of one criterion with all domains stated that the proposed domains are interrelated and together provide a total health system perspective that can facilitate care management and coordination.

Response. We thank commenters and agree that these eight domains can together provide a more comprehensive picture of the patient that can facilitate care management and coordination. We also believe that there will not be a significant increase in development

³⁴ <http://www.nih.gov/precisionmedicine/>.

³⁵ http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

burden to meet all the proposed domains because there will be developmental synergies in meeting all domains using the required LOINC® code set. Accordingly, we have adopted one criterion that requires certification to all eight proposed domains (not including SO/GI).

- *Transitions of Care*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(1) (Transitions of care)

We proposed to adopt a 2015 Edition certification criterion for “transitions of care” (“ToC”) that is a continuation and extension of the “ToC” certification criterion adopted as part of the 2014 Edition Release 2 final rule at § 170.314(b)(8). We proposed the following revisions and additions.

Updated C–CDA Standard

We proposed to adopt C–CDA Release 2.0 at § 170.205(a)(4) and noted that compliance with the C–CDA Release 2.0 cannot include the use of the “unstructured document” document-level template for certification to this criterion. To address “bilateral asynchronous cutover,” we proposed that the 2015 Edition “ToC” certification criterion reference both the C–CDA Release 1.1 and Release 2.0 standards and that a Health IT Module presented for certification to this criterion would need to demonstrate its conformance and capability to create and parse both versions (Release 1.1 and 2.0) of the C–CDA standards. While we recognized that this proposal was not ideal, we proposed this more conservative approach as a way to mitigate the potential that there would be interoperability challenges for transitions of care as different health care providers adopted Health IT Modules certified to the 2015 Edition criterion (including CCDA Release 2.0 capabilities) at different times. We requested comment on an alternative approach related to the creation of C–CDA-formatted documents. We noted that the adoption of C–CDA Release 2.0 would be applicable to all of the other certification criteria in which the C–CDA is referenced and that, unless C–CDA Release 2.0 is explicitly indicated as the sole standard in a certification criterion, we would reference both C–CDA versions in each of these criteria.

Comments. Commenters agreed that C–CDA Release 2.0 offered improvements compared to Release 1.1 for unifying summary care record requirements and better enabling

exchange of structured data between providers across disparate settings than previous versions. Commenters did not support requiring that Health IT Modules presented for certification would need to demonstrate its conformance and capability to send, receive, and parse both versions Release 1.1 and 2.0 of the C–CDA standards. Commenters stated that this proposed requirement would be too resource intensive, expressed concerns about the storage needed to store two versions of the C–CDA document, and would require systems to establish complex rules about handling content that is present in one version but not in the other. The majority of commenters instead recommended that we adopt a single version of the C–CDA standard that would ensure systems can correctly process both Releases 1.1 and 2.0, with many commenters specifically recommending Release 2.1 of C–CDA (HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015)³⁶ which the industry has developed, balloted, and published. Release 2.1 provides compatibility between Releases 2.0 and 1.1 by applying industry agreed-upon compatibility principles.³⁷ Release 2.1 also contains all the new document templates included in Release 2.0. Commenters also recommended an alternate pathway if we did not adopt Release 2.1 that would require:

- A 2015 Edition certified Health IT Module to be able to send documents conformant to C–CDA Release 2.0;
- A 2015 Edition certified Health IT Module to be able to parse both a C–CDA Release 1.1 and 2.0 document;
- A 2014 Edition certified Health IT Module to be able to parse a C–CDA Release 1.1 document, and display but not parse a document conformant to C–CDA Release 2.0.

A few commenters requested clarification on the different kinds of null values and guidance on what constitutes an “indication of none” since blank values will not meet the requirements of the corresponding measure for transitions of care for Stage 3 of the EHR Incentive Programs.

Response. We thank commenters for their suggestions to adopt Release 2.1 rather than require adherence to both versions Release 1.1 and Release 2.0. We agree that Release 2.1 largely provides

compatibility with Release 1.1 while maintaining many of the improvements and new templates in Release 2.0. While we thank commenters for the alternate suggested pathway regarding 2014 Edition certified health IT, this would require a revision to the existing 2014 Edition “ToC” certification criteria (§ 170.314(b)(1), § 170.314(b)(2), and § 170.314(b)(8)) that would require technology to be able to display a C–CDA document conformant with C–CDA Release 2.0. We did not propose this approach for public comment. Further, it would also be impractical and burdensome to implement as it would require forcing all health IT developers to bring back health IT certified to the 2014 Edition to update each product’s certification.

We believe that adopting Release 2.1 largely achieves the goal to ensure systems can send, receive, and parse both C–CDA documents formatted according to Release 1.1 or 2.0 and minimizes the burden raised by commenters. However, we are aware that a system developed strictly to Release 2.1 might not automatically support receiving Release 1.1 C–CDAs without additional development (e.g., additional generation and import effort since different vocabulary requirements apply in several places when comparing the two versions of the C–CDA). Therefore, we have adopted C–CDA Release 2.1 (both Volumes 1 and 2) as a requirement for the 2015 Edition “ToC” criterion at § 170.314(b)(1), and have also adopted the requirement that a Health IT Module must demonstrate its ability to receive, validate, parse, display, and identify errors to C–CDA Release 1.1 documents to ensure compatibility and interoperability. Note that for consistency, all 2015 Edition certification criteria that reference C–CDA creation (e.g., clinical information reconciliation and incorporation; view, download, and transmit to 3rd party) require conformance to Release 2.1. 2015 Edition certification criteria that include a “receipt” of C–CDA documents function (e.g., clinical information reconciliation and incorporation) will also require testing to correctly process C–CDA Release 1.1 documents for the reasons described above. This pathway ensures maximum interoperability while balancing the development burden.

Regarding the questions of clarification on the use of null values and what constitutes an “indication of none” for the purposes of meeting the EHR Incentive Program Stage 3 measure, this issue concerns the information needed to fulfill the “automated numerator recording” and “automated

³⁶ http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_CCDA_CLINNOTES_R1_DSTUR2.1_2015AUG.zip.

³⁷ http://wiki.hl7.org/index.php?title=Consolidated_CDA_R2.1_DSTU_Update.

measure calculation” functions proposed at §§ 170.315(g)(1) and (g)(2), respectively. This issue concerns the draft test procedure for §§ 170.315(g)(1) and (g)(2) as related to transitions of care, and we intend to update the test procedures to include guidance on how C–CDA R2.1 null values (including “indication of none”) are appropriately expressed by applying guidance from the HL7 Examples Task Force.

We also highly recommend that health IT developers and providers follow the guidance provided in the HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1—US Realm³⁸ that includes industry “best practices” guidance for consistent implementation of the C–CDA Release 1.1 standard, including for mapping Common MU Data Set elements into the C–CDA standard. It is our understanding that the industry is developing an update to this “companion guide” to provide guidance on implementing the C–CDA Release 2.1 standard. We encourage health IT developers to use the update to develop their products to the 2015 Edition criteria that reference C–CDA Release 2.1 when it becomes available.

C–CDA Document Template Types

We proposed to require that all certified Health IT Modules be able to parse C–CDA Release 2.0 documents formatted according to the following document templates:

- Continuity of Care Document (CCD);
- Consultation Note;
- History and Physical;
- Progress Note;
- Care Plan;
- Transfer Summary;
- Referral Note; and
- Discharge Summary.

These document templates include clarifications and enhancements relative to Release 1.1, as well as new document templates (*i.e.*, Care Plan, Referral Note, and Transfer Summary). We also proposed to prohibit the use of the unstructured document template.

Comments. Commenters were supportive of the new and clarified document templates for more specific use cases where a CCD may contain more information than is necessary. However, a number of commenters were concerned about the burden to certify all document templates, and noted that not all document templates were applicable to all settings. As such,

commenters suggested we require only the CCD, Referral Note, and (for inpatient settings only) Discharge Summary and allow health IT developers to determine which additional templates would be appropriate to offer for the settings and providers intended to be served by the product. A few commenters suggested that we not prohibit the use of the unstructured document template as it could be a stepping stone to help providers begin using the C–CDA standard and can be used to provide reports with images or scanned forms.

Response. We thank commenters for the comments, and acknowledge that some of the proposed C–CDA document templates may not be applicable to all settings. Therefore, we have required that certified Health IT Modules be able to parse C–CDA Release 1.1 and C–CDA Release 2.1 CCD, Referral Note, and (for inpatient settings only) Discharge Summary document templates for certification to this criterion. We encourage health IT developers and providers to work together to determine if additional C–CDA templates would be better suited for certain settings. For example, the CCD may contain more information than is necessary for some care transitions and other C–CDA document templates may provide a more succinct and/or targeted summary of a patient’s clinical information for certain settings. We note that C–CDA Release 2.1 includes the same document templates included in Release 2.0.

Regarding the use of the unstructured document template, we believe that it limits interoperability as data is not exchanged in a structured and standardized (*e.g.*, to certain vocabulary standards) manner. For the purposes of certification to this certification criterion, Health IT Modules cannot include the use of the unstructured document template.

Valid/Invalid C–CDA System Performance and Display

We proposed that Health IT Modules would need to demonstrate the ability to detect valid and invalid C–CDA documents, including document, section, and entry level templates for data elements specified in 2014 and 2015 Editions. Specifically, that this would include the ability to detect invalid C–CDA documents, to identify valid C–CDA document templates, to detect invalid vocabularies and codes not specified in either the C–CDA 1.1 or 2.0 standards or required by this regulation, and to correctly interpret empty sections and nullFlavor combinations per the C–CDA 1.1 or 2.0 standards. Last, we proposed that

technology must be able to display in human readable format the data included in a transition of care/referral summary document. We explained that we expected that Health IT Modules to have some mechanism to track errors encountered when assessing received C–CDA documents and we proposed that health IT be able to track the errors encountered and allow for a user to be notified of errors or review the errors produced. We stated these functionalities are an important and necessary technical prerequisite in order to ensure that as data in the system is parsed from a C–CDA for incorporation as part of the “clinical information reconciliation and incorporation” certification criterion the user can be assured that the system has appropriately interpreted the C–CDA it received.

Comments. There was overall support from commenters on the proposal to require Health IT Modules detect valid and invalid C–CDA documents. However, similar to the comments above, commenters did not support the proposal to require validation of both C–CDA Releases 1.1 and 2.0 because of the burden and complexity of processing two versions of the same standard. A few commenters were concerned with the proposed requirement for the receiving system to manage an incorrectly formatted C–CDA document, and requested that this burden should be on the sending system. A few commenters also requested clarification on whether the receiver is required to notify the sender of the C–CDA document of errors. Commenters also requested clarification on how validation and display would be tested as it would be unrealistic for health IT to accept every single code in a system. Last, some commenters were concerned about the “alert fatigue” a user could encounter if notified of every C–CDA error detected by the certified system.

Response. We thank commenters for their support of the proposal. As noted above, systems would be required to support validation and display for both Releases 1.1 and Release 2.1 to ensure compatibility and interoperability. We reiterate as noted above that systems will be tested to perform the validation and display functions for only the CCD, Referral Note, and (inpatient settings only) Discharge Summary templates.

Regarding the burden to the receiving system to process incorrectly formatted C–CDA errors, we note that all Health IT Modules certified to a 2015 Edition criterion that includes the functionality to create a C–CDA are also required to be certified to the “C–CDA Creation

³⁸ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=374.

Performance” certification criterion at § 170.315(g)(6). This certification criterion requires that systems are able to create C-CDA documents in accordance with a gold standard that we provide, thereby reducing the potential for errors in a C-CDA sent by an outgoing system (please refer to the “C-CDA creation performance” criterion in the preamble for further details).

However, we recognize that there may still be errors in created C-CDA documents from a sending system and therefore continue to believe in the value of the receiving system to process and validate C-CDA documents, including notifying the user of errors. We clarify that the error notification should be available to the receiving user. Regarding error notification, systems would be required to demonstrate its ability to notify the user of errors or allow the user to review the errors for the purposes of certification. Per commenters’ concerns about “alert fatigue,” we note there is no explicit requirement that the user be interrupted regarding the availability of errors. Rather, that the user needed to be able to access such errors. We anticipate that validation and display would be tested through visual inspection that test data in the form of C-CDA documents with and without errors can be correctly parsed and errors correctly identified.

We have finalized the requirement as part of this criterion that Health IT Modules must be able to detect valid and invalid transition of care/referral summaries received and formatted in accordance with C-CDA Release 1.1 and Release 2.1 for the CCD, Referral Note, and (inpatient settings only) Discharge Summary document templates, including detection of invalid vocabulary standards and codes, correct interpretation of empty sections and null combinations, recording of errors/notification of errors to the user, and the ability to display a human readable formatted C-CDA (for both Releases 1.1 and 2.1). We discuss additional clarifications regarding the display of C-CDA sections below.

Clinical Relevance of Summary Care Record Information

We have received feedback from providers expressing difficulty finding or locating the pertinent and relevant clinical information on a patient from a transition of care/referral summary received as a C-CDA document. Commenters have indicated that data included in a transition of care/referral summary document may be rendered and displayed as a long, multi-page document, which makes it challenging

for a provider to quickly find the clinical information they seek to make a care decision.

We note that CMS has finalized in the EHR Incentive Programs Stage 3 and Modifications final rule guidance that permits a provider and organization (*i.e.*, the “sender”) to define the “clinical relevance” of information sent in a summary care record depending on the circumstances, as best fits the organizational needs, and as relevant for the patient population.³⁹ CMS notes, however, that the sending provider has to have the ability to send all clinical notes or laboratory results in a summary care document if that level of detail is requested by the receiving provider.

While the guidance in the EHR Incentive Programs Stage 3 and Modifications final rule does address “clinical relevance” from the sending side and could result in a reduction in the quantity of data potentially viewed by a recipient as “unnecessary” or not useful, we recognize that certain patients, such as those with complex and/or chronic conditions may have a transition of care/referral summary sent to receiving providers with large quantities of data included. In that respect, we included as part of the 2014 Edition Final Rule a specific “section views” capability in the “transitions of care” certification criterion (adopted at 45 CFR 170.314(b)(1)(iii)(C)), which we described as having been added to the certification criterion in order to make sure that health IT would be able to extract and allow for individual display each additional section or sections (and the accompanying document header information (*i.e.*, metadata)) that were included in a transition of care/referral summary received and formatted in accordance with the Consolidated CDA (77 FR 54219).

We indicated that this functionality would be useful in situations when a user wanted to be able to review other sections of the transition of care/referral summary that were not incorporated (as required by this certification criterion at 45 CFR 170.314(b)(1)), such as a patient’s procedures and smoking status, and that the technology would need to provide the user with a mechanism to select and just view those sections *without* having to navigate through what could be a lengthy document.

The section views capability remains as part of the 2015 Edition version of this criterion. Additionally, to address comments that raised concerns and

requested that we act to address a C-CDA’s “length” and users’ ability to more easily navigate to particular data within the C-CDA, we have included more precise requirements in this portion of the certification criterion. Specifically, the 2015 Edition version includes that a user must be able to: (1) Directly display only the data within a particular section, (2) set a preference for the display order of specific sections, and (3) set the initial quantity of sections to be displayed. We also clarify that the sole use of the CDA.xsl style sheet provided by HL7 to illustrate how to generate an HTML document from a CDA document will not be acceptable to meet these requirements. We believe these clarifications will help address stakeholder concerns regarding the difficulty finding or locating the pertinent and relevant clinical information on a patient from a ToC/referral summary received as a C-CDA document. We intend to ensure that the test procedure for this criterion thoroughly tests these aspects consistent with the certification criterion’s requirements. We also strongly urge the health IT industry to dedicate additional focus toward improving the rendering of data when it is received. Putting such data to use in ways that enable providers to quickly view and locate the information they deem necessary can help improve patient care and prevent important information from being inadvertently missed. We further note that standards experts are aware of the stakeholder concerns discussed above, and that the HL7 Structured Documents Work Group is working on contributing positive momentum to this issue.⁴⁰ The HL7 Structured Documents Work Group’s work involves developing guidance on the “relevant” data that should be sent by the sender. We encourage health IT developers to participate in this process and implement the industry principles arising out of this project.

Edge Protocols

We proposed to “carry-over” a requirement from the 2014 Edition Release 2 “transitions of care” criterion at § 170.314(b)(8) that would require a certified Health IT Module be able to send and receive transition of care/referral summaries through a method that conforms to the ONC Implementation Guide for Direct Edge Protocols, Version 1.1 at § 170.202(d).

Comments. Commenters were generally in support of requiring one of

³⁹ Please see the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

⁴⁰ <http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1183>.

the four Edge Protocols designated in the ONC IG for Direct Edge Protocols. One commenter was concerned that the edge protocols offer no additional value for those that have already implemented Direct.

Response. As stated in the 2014 Edition Release 2 final rule, we believe that adoption of the ONC IG for Direct Edge Protocols can improve the market availability of electronic health information exchange services for transitions of care by separating content from transport related to transitions of care. We believe that certification to the Direct Edge Protocols IG can also enable greater certainty and assurance to health IT developers that products certified to this IG have implemented the IG's edge protocols in a consistent manner (79 FR 54437). As such, we have finalized the requirement that a certified Health IT Module be able to send and receive transition of care/referral summaries through a method that conforms to the ONC Implementation Guide for Direct Edge Protocols, Version 1.1.

We note that we inadvertently left out a provision of the proposed regulation text related to Edge Protocol requirements. As noted above and in the Proposed Rule, we intended to "carry over" the Edge Protocol requirements included in § 170.314(b)(8) for this criterion. Therefore, we have added to the provision in § 170.315(b)(1)(i)(A) about sending transition of care/referral summaries through a method that conforms with the Edge Protocol and a requirement that it must also lead to the summaries being processed by a service that has implemented Direct. This addition parallels the Direct Edge Protocol "receiving" requirements we proposed and have finalized. It also clarifies a consistent set of technical capabilities for sending the Edge Protocol and technologies interacting with services that have implemented Direct, which again are the exact same requirements included in § 170.314(b)(8) that we intended to duplicate in this 2015 Edition criterion.

XDM Package Processing

We proposed to include a specific capability in this certification criterion that would require a Health IT Module presented for certification that is also being certified to the SMTP-based edge to demonstrate its ability to accept and process an XDM package it receives, which would include extracting relevant metadata and document(s). We explained that this additional requirement only applies to a Health IT Module presented for certification with an SMTP-based edge implementation and not an XDR edge implementation.

Because we expect XDM packaging to be created in accordance with the specifications included in IHE IT Infrastructure Technical Framework Volume 2b, Transactions Part B—Sections 3.29—2.43, Revision 7.0, August 10, 2010 (ITI TF–2b),⁴¹ we proposed to adopt this as the standard at § 170.205(p)(1) for assessing whether the XDM package was successfully processed.

Comments. Commenters were supportive of the proposal to demonstrate XDM package processing. Many commenters recommended that processing on receipt depends on metadata in the XDM package that should be aligned with the general metadata in Appendix B of the IHE Data Access Framework Document Metadata Based Access Implementation Guide that was published for public comment on June 1, 2015.⁴² One commenter recommended that the certification criterion point specifically to section 3.32.4.1.4 of ITI TF–2b.

Response. We thank commenters for their support of the proposal and have finalized this requirement that Health IT Modules certified to an SMTP-based edge protocol be able to receive and make available the contents of an XDM package formatted in accordance with ITI TF–2b, which we have adopted at § 170.205(p)(1). We note that the ONC Implementation Guide for Direct Edge Protocols adopted at § 170.202(d) and required for this criterion as discussed above references the guidance in the ONC XDR and XDM for Direct Messaging Specification for proper use of metadata that is aligned with the IHE Data Access Framework Document Metadata Based Access IG. Therefore, we do not believe it is necessary to reference the IHE IG as these metadata requirements are already referenced and required for this criterion. Similarly, our requirement to adhere to the ITI TF–2b would include any specific section required in the standard, and thus we do not need to reference a specific section.

SMTP-based transport systems use standard Multi-Purpose Internet Mail Extension (MIME) to identify email attachments and to enable receiving computer systems to process attachments seamlessly. For example, a MIME type of "text/html" identifies text styled in HTML format. C–CDA documents are commonly identified using "text/xml" and "application/xml"

In addition, XDM packages are commonly identified with "application/zip" and "application/octet-stream" MIME types. However, these MIME types have not been standardized by the community for transporting C–CDA and XDM files. Systems could potentially use other valid MIME types to send the documents. While these standard MIME types provide sufficient information for receiving systems to render content, they do not provide a way to distinguish the C–CDA and XDM documents from all the other documents that could be sent using the same MIME types. Until an appropriate set of MIME types are developed that can uniquely identify C–CDA and XDM, there is widespread acknowledgement that the receiving systems should accept all common MIME types, and use the information within the actual documents, to process C–CDA and XDM accordingly. Hence, in order to facilitate interoperability, we expect Health IT Modules to be able to support all commonly used MIME types when receiving C–CDA and XDM packages. We intend to update the test procedure to include guidance on specific MIME types that we expect Health IT Modules to support, at a minimum.

Common Clinical Data Set

We proposed to require Health IT Modules to enable a user to create a transition of care/referral summary that includes, at a minimum, the Common Clinical Data Set for the 2015 Edition that includes references to new and updated vocabulary standards code sets.

Comments. Commenters were supportive of this proposal overall. A few commenters were concerned about specific data elements in the proposed 2015 Edition Common Clinical Data Set definition.

Response. We thank commenters for their support and have adopted the requirement that Health IT Modules enable a user to create a transition of care/referral summary that includes the 2015 Edition Common Clinical Data Set at a minimum. We address the specific data elements in the 2015 Edition Common Clinical Data Set definition in under section III.B.3 of this final rule.

Encounter Diagnoses

We proposed to continue the requirement from the 2014 Edition "ToC" certification criterion that a Health IT Module must enable a user to create a transition of care/referral summary that also includes encounter diagnoses using either SNOMED CT® (September 2014 Release of the U.S.

⁴¹ http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol2b_FT_2010-08-10.pdf.

⁴² http://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_IG_DAF_National%20Extension_Rev1.0_PC_2015-06-01.pdf.

Edition as a baseline for the 2015 Edition) or ICD-10-CM codes.

Comments. One commenter recommended solely the use of ICD-10-CM for encounter diagnoses and certification. Another commenter requested clarification on whether the encounter diagnoses are meant to be “billing diagnoses” and whether the health IT would need to include all billing diagnoses for encounters or just the primary encounter, and how primary would be determined.

Response. As stated in our 2014 Edition final rule (77 FR 54178 and 54220), we believe that SNOMED CT® is the more appropriate vocabulary for clinical purposes and provides greater clinical accuracy. However, it may be beneficial for inpatient Health IT Modules to be certified to and support the use of ICD-10-CM to represent diagnoses, and finalized the 2014 Edition “transitions of care—create and transmit” criterion at § 170.314(b)(1) to allow for either ICD-10-CM or SNOMED CT®. We continue this policy and have finalized the requirement for this 2015 Edition “ToC” certification criterion that a Health IT Module enable a user to create a transition of care/referral summary that includes encounter diagnoses using either SNOMED CT® (September 2015 Release of the U.S. Edition as a baseline for the 2015 Edition⁴³) or ICD-10-CM codes.

We note that our certification requirement does not dictate what encounter diagnoses providers would include in a transitions of care document, only that certified Health IT Modules can enable a provider to include encounter diagnoses using SNOMED CT® or ICD-10-CM.

“Create” and Patient Matching Data Quality

As a part of the “Create” portion of the “ToC” criterion in the 2015 Edition, we proposed to require a Health IT Module to be able to create a transition of care/referral summary that included a limited set of standardized data in order to improve the quality of the data that could potential be used for patient matching by a receiving system. The proposed standardized data included: First name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex, with constrained specifications for some of the proposed standardized data.

⁴³ We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our decision to adopt this version.

Comments. There was general support for requiring the proposed data elements to be exchanged in order to improve patient matching. Some commenters were concerned with conflicts between the proposed approach and existing systems’ algorithms and patient matching protocols. A few commenters recommended that we wait until there is a consensus-based patient matching standard before adopting requirements for certification. A few commenters also noted that the proposal does not address data quality.

Response. We note that systems can continue to use their existing algorithms and patient matching protocols and that our proposed approach was not intended to conflict with any existing practice. We reiterate that the proposed data elements stem from the HITPC’s and HITSC’s recommendations and findings from the 2013 ONC initiative on patient matching as described in the Proposed Rule (80 FR 16833–16834). We continue to believe these recommendations represent a first step forward that is consensus-based. We agree that the proposal did not address data quality in the sense that it would improve the “source’s” practices and procedures to collect highly accurate and precise data. However, we believe that including standards for the exchange of certain data elements could improve interoperability and provides an overall level of consistency around how the data are represented. We encourage ongoing stakeholder efforts focused on improving patient matching through better data quality processes and will continue to monitor and participate in these activities.

Comments. Commenters recommended that we ensure alignment between the proposed data elements and corresponding standards with those in the C-CDA standard.

Response. We have performed an analysis of the proposed data elements and standards with those in C-CDA Release 2.1 and have made some revisions as described below. In some cases, the ONC method may be more constrained than what is in C-CDA Release 2.1 and we believe there will be no conflict. Rather the additional constraint is intended to promote patient matching and interoperability. We also address standards for specific elements below.

Comments. Commenters suggested that we should not reference the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 for suffix as it puts JR, SR, I, II, III, IV, and V in the same field as RN, MD, PHD, and ESQ. Commenters felt that these suffixes

should be kept separate as it could be confusing if a patient has more than one suffix (e.g., JR and MD). Individuals may also not use both suffixes in all circumstances, so it may be difficult to match records using both.

Response. We agree with the comments and have not adopted the constraint for suffix to adhere to the CAQH standard. We recommend that health IT developers and providers follow the guidance for suffix in C-CDA Release 2.1 for exchange, which allows for an additional qualifier for any suffix provided with the last name field.

Comments. One commenter noted that the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 is intended for normalization of information upon receipt rather than at the point of sending. Pre-normalization can lead to data loss and detract from patient matching. Therefore the commenter recommended ONC not require the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 for normalizing last name in the sending of transition of care/referral summary documents and rather point to it as guidance for receiving systems.

Response. We agree with the commenter, and have not adopted the constraint for last name normalization in accordance with the CAQH standard. We recommend that health IT developers and providers follow the guidance for last name in C-CDA Release 2.1 for exchange of transition of care/referral summary documents.

Comments. A few commenters suggested that the concept of “maiden name” is not used in all cultures and is also gender-specific. Some commenters noted that some nationalities, cultures, or ethnic groups do not use this term and, in other cases, an individual may adopt more than one family name during marriage. There are other cases where the last name or family name has been legally changed for other situations. Most commenters recommended we instead use another term that broadly captures these situations and allows for aliases that a patient may use in these circumstances.

Response. We thank commenters for the feedback and have revised “maiden name” to “previous name” to accommodate for any other aliases including the situations described above by the commenters. We note that the C-CDA Release 2.1 contains a field for “birth name” that can accommodate this information.

Comments. A number of commenters were concerned about including place

of birth in the list of data elements as there is a lack of standards on representing the place of birth. Some systems include city, county, state, and country, while other systems may only include some of these elements. Therefore, these commenters stated that it would be difficult to standardize on place of birth as proposed and it would offer no additional value for improving patient matching.

Response. We agree with commenters that the lack of standards for representing place of birth would not improve patient matching at this time and, therefore, have not finalized this data element requirement.

Comments. A few commenters noted concerns about including the hour, minute, and second of the date of birth, and suggested that the time zone is needed to correctly match records.

Response. We note that as proposed in the 2015 Edition, the hour, minute, and second of the date of birth were optional or conditional fields based on whether they were included. Since we have not finalized the proposed requirement to include place of birth, we have revised the requirement as follows. We clarify that for the purposes of certification that the hour, minute, and second for a date of birth are optional for certification. If a product is presented for certification to this optional provision, the technology must demonstrate that the correct time zone offset is included.

Comments. One commenter supported the proposal to include phone number in the list of patient match elements. Another commenter recommended we specify a standard for representing phone number.

Response. We clarify that we proposed that the phone number must be represented in the ITU format specified in the International Telecommunication Union (ITU)'s ITU-T E.123⁴⁴ and ITU-T E.164 standards.⁴⁵ These are the best available industry standards for representing phone number and we have adopted them for representing phone number in this certification criterion.

Comments. As stated above, commenters suggested we perform an analysis of the standards required by the C-CDA standard and resolve any inconsistencies with our proposal.

Response. In our analysis of the proposed data elements with the C-CDA Release 2.1 standard as suggested by commenters, we found that the C-CDA Release 2.1 standard is not able to

distinguish between historical and current address as proposed. Because of the discrepancy between our proposal and what the C-CDA Release 2.1 can accommodate, we have revised the requirement to "address" (not specified as historical or current). We note that C-CDA Release 2.1 can accommodate more than one address. It is our understanding that the underlying parent C-CDA standard (*i.e.*, CDA) included the ability to send a useable period with the address to specify different addresses for different times of the year or to refer to historical addresses. However, this useable period was removed from C-CDA as it did not have enough use. We intend to work with stakeholders going forward in assessing whether the useable period should be included in future versions of the C-CDA standard or whether there are other methods for distinguishing historical or current address for consideration in future rulemaking.

Comments. A number of commenters recommended ONC adopt the US Postal Service (USPS) standard for representing address. Commenters noted that the standard is widely supported by health care organizations today, and that it is recommended by the American Health Information Management Association.⁴⁶ Another commenter recommended we consider adoption of the GS1 Global Location Number standard.

Response. We thank commenters for the input. At this point in time and since this patient matching requirement focuses on the use and representation of address in the C-CDA standard, we believe that use of the C-CDA standard's built-in requirements is the best, most incremental path forward. We note the C-CDA Release 2.1 standard references the HL7 postal format. Additionally, testing and validation to the HL7 postal format in the C-CDA standard is already available as part of 2014 Edition "transitions of care" testing to C-CDA Release 1.1. We see a need for continued industry work to determine the appropriateness of existing standards and tools for normalizing postal address for health care use cases such as matching of electronic patient health records, and intend to work with stakeholders in this space. Thus, we look forward to continuing to work with stakeholders to analyze the USPS address standard⁴⁷ and other industry standards with respect to any future updates to the

C-CDA to bring about industry-wide consistency. We anticipate the C-CDA validation tool for 2015 Edition "transitions of care" testing will carry over the 2014 Edition testing and suggest that health IT developers and implementers adhere to the guidance in C-CDA Release 2.1 on the use of the HL7 postal format.

Comments. A few commenters suggested we consider the addition of data elements to the proposed list, such as a social security number or the last four digits of a social security number.

Response. We thank commenters for the suggestions but do not agree and have not accepted these suggestions. We have evaluated the list proposed in the Proposed Rule⁴⁸ and continue to believe that it represents a good first step toward improving patient matching in line with the HITSC, HITPC, and ONC 2013 patient matching initiative recommendations. We intend to continue our work in developing patient matching best practices and standards, including evaluating the feasibility, efficacy, and, in some cases, the legality of specifying other data elements for patient matching. We may propose to expand this list or adopt a more sophisticated patient match policy in future rulemaking as standards mature.

Comments. A few commenters noted that a 100% patient match is impossible to achieve in every instance.

Response. We note that our proposal only concerns the ability of a certified Health IT Module to create a transition of care/referral summary document that contains the proposed data elements in accordance with the specified standards/constraints. The proposal would not require a system to demonstrate how it performs patient matching with these data for certification. As noted above, we believe the algorithms and patient matching protocols are best left to health IT systems and providers to determine at this point in time. While the HITPC recommended⁴⁹ that we should develop, promote, and disseminate best practices, there is not an industry-wide standard for patient matching protocols that is ready to require as a condition of certification. We intend to continue working with the industry to develop these best practices, and will evaluate at a later point if certification would

⁴⁸ First name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex, with constrained specifications for some of the proposed standardized data.

⁴⁹ http://www.healthit.gov/FACAS/sites/default/files/standards-certification/8_17_2011Transmittal_HITSC_Patient_Matching.pdf.

⁴⁴ <http://www.itu.int/rec/T-REC-E.123-200102-1/e>.

⁴⁵ <http://www.itu.int/rec/T-REC-E.164-201011-1/en>.

⁴⁶ <http://perspectives.ahima.org/wp-content/uploads/2014/12/PatientMatchingAppendixA.pdf>.

⁴⁷ <http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf>.

confer additional benefit for improving patient matching. Until such protocols are established and mature, our requirement addresses the HITPC's first recommendation, which is to provide standardized formats for demographic data fields.

In consideration of public comments, we have finalized the requirement that Health IT Modules must be able of creating a transition of care/referral summary in accordance with just C-CDA Release 2.1 as part of this certification criterion that includes the following data formatted to the associated standards/constraints where applicable:

- First name;
- Last name;
- Previous name;
- Middle name (including middle initial);
- Suffix;
- Date of birth—The year, month, and day of birth are required fields. Hour, minute, and second are optional fields; however, if hour, minute, and second are provided then the time zone offset must be included. If date of birth is unknown, the field should be marked as null;

- Address;
- Phone number—Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123⁵⁰ and ITU-T E.164⁵¹ which we are adopting at § 170.207(q)(1). If multiple phone numbers are present, all should be included; and

- Sex in accordance with the standard we are adopting at § 170.207(n)(1).

We note that we corrected the date of birth requirements to specify the year, month, and day of birth as the required fields. We previously inadvertently listed “date” instead of “day.”

Direct Best Practices

Given feedback from stakeholders regarding health IT developers limiting the transmission or receipt of different file types via Direct, we reminded all stakeholders in the Proposed Rule of the following best practices for the sharing of information and enabling the broadest participation in information exchange with Direct: <http://wiki.directproject.org/Best+Practices+for+Content+and+Workflow>. We did not include a proposal or request for comment related to this guidance.

Comments. One commenter recommended we review the challenges and solutions recommended by the DirectTrust in Chapter 2, Chapter 7 and

Chapter 8 of the white paper, “A Report on Direct Trust Interoperability Testing and Recommendations to Improve Direct Exchange.”⁵²

Response. As we did not include a proposal or request for comment, we thank the commenter for the recommendation and will review the recommended material.

Certification Criterion for C-CDA and Common Clinical Data Set Certification

We noted that no proposed 2015 Edition certification criterion includes just the C-CDA Release 2.0 and/or the Common Clinical Data Set, particularly with the 2015 Edition not including a proposed “clinical summary” certification criterion as discussed in the 2015 Edition Proposed Rule (80 FR 16850). We requested comment on whether we should adopt a separate 2015 Edition certification criterion for the voluntary testing and certification of health IT to the capability to create a summary record formatted to the C-CDA Release 2.0 with or without the ability to meet the requirements of the Common Clinical Data Set definition.

Comments. We received comments in favor of adopting a new 2015 Edition criterion that includes just the ability of a Health IT Module to enable a user to create a transition of care/summary care record in accordance with C-CDA Release 2.0 and with the ability to meet the requirements of the Common Clinical Data Set.

Response. We have adopted two new 2015 Edition certification criteria (with no relation to the EHR Incentive Programs) that include just the ability of a Health IT Module to enable a user to create (one criterion) and receive (one criterion) a transition of care/referral summary in accordance with C-CDA Release 2.1 (create) and both C-CDA Releases 1.1 and 2.1 (receive) and with the ability to meet the requirements of the Common Clinical Data Set at § 170.315(b)(4) and § 170.315(b)(5), respectively. For the certification criterion adopted to “create” a transition of care/referral summary at § 170.315(b)(4), we have also, for consistency, include the same patient matching data as referenced by the “ToC” certification criterion. We refer readers to the “Common Clinical Data Set summary record—create” and “Common Clinical Data Set summary record—receive” certification criteria in this section of the preamble for a more detailed description of the rationale and

specific requirements of the new certification criteria.

C-CDA Data Provenance Request for Comment

We requested comment on the maturity and appropriateness of the HL7 IG for CDA Release 2: Data Provenance, Release 1 (US Realm) (DSTU)⁵³ for the tagging of health information with provenance metadata in connection with the C-CDA, as well as the usefulness of this IG in connection with certification criteria, such as “ToC” and “VDT” certification criteria.

Comments. Although commenters were supportive of the usefulness of data provenance, the majority of commenters did not think the HL7 Data Provenance standard was mature for adoption at this point in time.

Response. We thank commenters for their input and will continue to monitor the industry uptake and maturity of the HL7 Data Provenance standard in consideration of future rulemaking.

• Clinical Information Reconciliation and Incorporation

2015 Edition Health IT Certification Criterion

§ 170.315(b)(2) (Clinical information reconciliation and incorporation)

We proposed to adopt a 2015 Edition “clinical information reconciliation and incorporation” certification criterion that is a revised (but largely similar to the 2014 Edition Release 2) version of the “clinical information reconciliation and incorporation” criterion adopted at § 170.314(b)(9). First, we proposed that Health IT Modules must be able to incorporate and reconcile information upon receipt of C-CDA's formatted to both Release 1.1 and Release 2.0 for similar reasons (e.g., for compatibility with Release 1.1) as proposed for the “ToC” criterion described above.

Comments. Commenters were generally supportive of the proposal to adopt a criterion for “clinical information reconciliation and incorporation” for interoperability.

Response. We thank commenters for their support and have adopted a 2015 Edition criterion for “clinical information reconciliation and incorporation” with the following changes and clarifications as discussed below.

Comments. Similar to the comments we received for the “ToC” criterion, commenters were not in favor of the proposed requirement to support both

⁵⁰ <http://www.itu.int/rec/T-REC-E.123-200102-1/e>.

⁵¹ <http://www.itu.int/rec/T-REC-E.164-201011-1/en>.

⁵² <http://static1.1.sqspcdn.com/static/f/1340919/26054983/1426686689687/Report+on+DirectTrust+Interoperability+Testing.pdf?token=A0DNBiAqjj2YzuhUTn4vnBMrVI%3D>.

⁵³ http://wiki.hl7.org/index.php?title=HL7_Data_Provenance_Project_Space and http://gforge.hl7.org/gforge/project/cbccc/frs/?action=FrsReleaseBrowse&frs_package_id=240.

versions of C-CDA Release 1.1 and 2.0 because of the burden to receive and process two versions of the same standard.

Response. As discussed in the preamble of the “ToC” criterion above, we have adopted a requirement that systems must be able to receive and correctly process documents formatted to both C-CDA Releases 1.1 and 2.1. While C-CDA Release 2.1 largely addresses compatibility issues with Release 1.1 and reduces the burden for systems receiving both versions, we are aware that a system developed strictly to Release 2.1 might not automatically support receiving Release 1.1 C-CDAs without additional development. Therefore, this criterion will focus on functionalities to receive, incorporate, and reconcile information from a C-CDA formatted to Releases 1.1 and 2.1.

C-CDA Document Templates and Reconciliation

We proposed that a certified Health IT Module be able to receive, reconcile, and incorporate information from the C-CDA Release 2.0 CCD, Discharge Summary, and Referral Note document templates at a minimum. Note that we incorrectly referenced the “Referral Summary” document template. There is no “Referral Summary” document template and we intended the “Referral Note” document template.

Comments. We did not receive specific comments regarding the C-CDA document templates proposed for this criterion.

Response. Although we did not receive comments regarding the C-CDA document templates for this certification criterion, we maintain the consistency decision discussed in the “ToC” criterion to require incorporation and reconciliation of information from the C-CDA Releases 1.1 and 2.1 CCD, Referral Note, and (for inpatient settings only) Discharge Summary document templates. We believe this will provide consistency between the minimum certification requirements for systems creating and sending C-CDA documents for transitions of care and this criterion for the receipt, incorporation, and reconciliation of C-CDA information.

Data for Reconciliation

We proposed that a Health IT Module must be able to reconcile and incorporate, at a minimum: problems, medications, and medication allergies from multiple C-CDAs, with testing for this specific system performance to verify the ability to incorporate valid C-CDAs with variations of data elements to be reconciled (*e.g.*,

documents with no medications, documents having variations of medication timing data). We also proposed that problems be incorporated in accordance with the September 2014 Release of the U.S. Edition of SNOMED CT® and that medications and medication allergies be incorporated in accordance with the February 2, 2015 monthly version of RxNorm as a baseline and in accordance with our “minimum standards code sets” policy.

Comments. A few commenters suggested we include additional data for incorporation and reconciliation, such as food allergies and intolerances, labs, and immunizations.

Response. As stated in the 2014 Edition final rule, we continue to believe that problems, medications, and medication allergies are the minimum data that should be reconciled and incorporated from a C-CDA (77 FR 54223). We note that this minimum requirement for certification would not prohibit health IT developers from including functionality to reconcile and incorporate a broader set of information from a C-CDA, which is something we encourage developers to pursue.

Comments. One commenter suggested that a provider may use different functionality for the reconciliation of medications distinct from the medication allergies and/or problems, and recommended that that certification criterion should allow for distinct or combined reconciliation approaches.

Response. We clarify that the certification criterion would allow for distinct (individual) or combined reconciliation functions for medications, medication allergies, and problems to be implemented so long as all the functions can be demonstrated.

Comments. Commenters were supportive of testing for this criterion to verify a Health IT Module’s ability to incorporate valid C-CDAs with variations in the data elements to be reconciled. Commenters believed this would reasonably test the real-world variation that may be found in C-CDA documents.

Response. We thank commenters for their support and intend for testing to verify a certified Health IT Module’s ability to incorporate valid C-CDAs with variations in the data elements.

C-CDA Creation for Validation of Accurate Reconciliation

We proposed to require that a C-CDA be created based on the reconciliation and incorporation process in order to validate the incorporation results. We expected that the generated C-CDA would be verified using test tools for conformance and can be checked

against the information that was provided to incorporate.

Comments. We received mixed feedback on this proposal. Some commenters were concerned that this requirement would not provide added benefit for Health IT Module users or patients. Other commenters noted that this requirement would be adding in a “create” function to this criterion, which they thought contradicted the modularity we previously introduced in the 2014 Edition Release 2 final rule when we made modifications to the 2014 Edition “transitions of care” and “clinical information reconciliation” criteria.

Response. We believe that the creation of a C-CDA based on the reconciliation and incorporation process will improve and automate the testing and verification process. While there are other methods of verifying reconciliation, such as queries and list displays, an automated verification through the use of test tools provides the most assurance that the information was reconciled and incorporated correctly. We do not believe this requirement will add unnecessary burden as it is our understanding that systems that receive, incorporate, and reconcile C-CDA information can also create a C-CDA. Furthermore, the purpose of this additional portion of the certification criterion is to increase provider assurance that the incorporation performed by a system post-reconciliation is accurate and complete.

With respect to the comments that mentioned an apparent contradiction with the requirement for “creating” a C-CDA as part of this certification criterion, we disagree, and remind commenters that the changes we made in the 2014 Edition Release 2 final rule were to better position the “incorporation” functionality in the right certification criterion (79 FR 54438–54439). Therefore, we have adopted the requirement that Health IT Modules be able to create a C-CDA Release 2.1 based on the reconciliation and incorporation process that will be verified during testing and certification. Note that this requirement applies to the ability to create a C-CDA formatted to the C-CDA Release 2.1 CCD document template only.

Comments. One commenter asked for clarification on whether the proposed regulation text “technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient” means that Health IT Modules must be able to auto-match to the correct patient. Commenters noted that

many systems allow for manual match, and that an auto-match may not be the most appropriate method to match patient records.

Response. We clarify that it was not our intention to prescribe how patient match is performed for this criterion. We have revised the regulation text to reflect that the technology must demonstrate that the received transition of care/referral summary document can be properly matched to the correct patient. We leave the flexibility to the health IT developer and provider to determine the best method for patient match.

Comments. A few commenters were concerned with the proposed requirement that for each list type (*i.e.*, medications, medication allergies, or problems) the Health IT Module must simultaneously display the data from at least two sources. Commenters noted that there would not be two sources if the patient is new to the receiving system.

Response. We reiterate that for the purposes of testing and certification, Health IT Modules must demonstrate the ability to simultaneously display the data from at least two sources. While the commenters' point is fair it is not within scope for the purposes of testing and certification, which focuses on when there is data to reconcile. In other words, the purpose of this certification criterion is, in part, to assess technology's capability to reconcile data from two sources. Testing and certification is focused on ensuring that that functionality exists and performs correctly. Additionally, the criterion does not address the totality of capabilities that may be present in the technology. In cases where a new patient presents this specific functionality may not be applicable or used at all.

• *Electronic Prescribing*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(3) (Electronic prescribing)

We proposed to adopt a 2015 Edition certification criterion for e-prescribing that is revised in comparison to the 2014 Edition "e-prescribing" criterion (§ 170.314(b)(3)).

First, we proposed to require a Health IT Module certified to this criterion be able to receive and respond to additional National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Implementation Guide Version 10.6 (v10.6) transactions or segments in addition to the New Prescription transaction, namely Change Prescription, Refill Prescription, Cancel Prescription, Fill Status, and Medication History. We proposed to require that a Health IT Module be able to send and receive end-to-end prescriber-to-receiver/sender-to-prescriber transactions (bidirectional transactions). The proposed transactions and reasons for inclusion for testing and certification are outlined in Table 5 below.

TABLE 5—PROPOSED ADDITIONAL⁵⁴ NCPDP SCRIPT v10.6 TRANSACTIONS FOR TESTING AND CERTIFICATION TO e-PRESCRIBING CERTIFICATION CRITERION

NCPDP SCRIPT v10.6 transaction or segment	Use case(s)	Problem addressed/value in testing for certification
Change Prescription (RXCHG, CHGRES).	<ul style="list-style-type: none"> Allows a pharmacist to request a change of a new prescription or a "fillable" prescription. Allows a prescriber to respond to pharmacy requests to change a prescription. 	Facilitates more efficient, standardized electronic communication between prescribers and pharmacists for changing prescriptions.
Cancel Prescription (CANRX, CANRES).	<ul style="list-style-type: none"> Notifies the pharmacist that a previously sent prescription should be canceled and not filled. Sends the prescriber the results of a prescription cancellation request. 	Facilitates more efficient, standardized electronic communication between prescribers and pharmacists for cancelling prescriptions.
Refill Prescription (REFREQ, REFRES).	<ul style="list-style-type: none"> Allows the pharmacist to request approval for additional refills of a prescription beyond those originally prescribed. Allows the prescriber to grant the pharmacist permission to provide a patient with additional refills or decline to do so. 	Facilitates more efficient, standardized electronic communication between prescribers and pharmacists for refilling prescriptions.
Fill Status (RXFILL)	Allows the pharmacist to notify the prescriber about the status of a prescription in three cases: (1) To notify the prescriber of a dispensed prescription, (2) to notify the prescriber of a partially dispensed prescription, and (3) to notify a prescriber of a prescription not dispensed.	Allows the prescriber to know whether a patient has picked up a prescription, and if so, whether in full or in part. This information can inform assessments of medication adherence.
Medication History (RXHREQ, RXHRES).	<ul style="list-style-type: none"> Allows a requesting entity to generate a patient-specific medication history request. The responding entity can respond, as information is available, with a patient's medication history, including source, fill number, follow-up contact, date range. 	Allows a requesting entity to receive the medication history of a patient. A prescriber may use this information to perform medication utilization review, medication reconciliation, or other medication management to promote patient safety.

We solicited comment on other NCPDP SCRIPT v10.6 transactions that should be considered for testing and certification, and for what use cases/value, and the factors to consider for

⁵⁴ We proposed to keep the "New Prescription" transaction for testing and certification.

end-to-end prescriber-to-receiver testing.

Second, we proposed to require that a Health IT Module certified to this criterion enable a user to enter, receive, and transmit codified Sig instructions in a structured format in accordance with NCPDP Structured and Codified Sig Format Implementation Guide v1.2

which is embedded within NCPDP SCRIPT v10.6 for certification to the e-prescribing criterion in the 2015 Edition.⁵⁵ We proposed this because we

⁵⁵ NCPDP's Structured and Codified Sig Format Implementation Guide v1.2 is within the NCPDP SCRIPT v10.6 standard. <https://www.ncdp.org/NCPDP/media/pdf/StandardsMatrix.pdf>.

believe standardizing and codifying the majority of routinely prescribed directions for use can promote patient safety, as well as reduce disruptions to prescriber workflow by reducing the number of necessary pharmacy call-backs. We proposed that this requirement apply to the New Prescription, Change Prescription, Refill Prescription, Cancel Prescription, Fill Status, and Medication History prescription transactions or segments as we understood that the NCPDP Structured and Codified Sig Format can be used for all NCPDP SCRIPT v10.6 prescription transactions that include directions for medication use. We also proposed to require that a Health IT Module include all structured Sig segment components enumerated in NCPDP SCRIPT v10.6 (i.e., Repeating Sig, Code System, Sig Free Text String, Dose, Dose Calculation, Vehicle, Route of Administration, Site of Administration, Sig Timing, Duration, Maximum Dose Restriction, Indication and Stop composites).

We solicited comment on whether we should require testing and certification to a subset of the structured and codified Sig format component composites that represent the most common Sig instructions rather than the full NCPDP Structured and Codified Sig Format Implementation Guide v1.2. NCPDP published recommendations for implementation of the structured and Codified Sig format for a subset of component composites that represent the most common Sig segments in the NCPDP SCRIPT Implementation Recommendations Version 1.29.⁵⁶

Third, we proposed that a Health IT Module certified to this criterion be capable of limiting a user's ability to electronically prescribe all medications only in the metric standard, and be capable of always inserting leading zeroes before the decimal point for amounts less than one when a user electronically prescribes medications. We also proposed that the Health IT Module not allow trailing zeroes after a decimal point. We stated our intent for proposing these requirements was to support more precise prescription doses in order to reduce dosing errors and improve patient safety.

Last, we proposed to adopt and include the February 2, 2015 monthly version of RxNorm in this criterion as the baseline version minimum standards code set for coding medications.

Comments. Many commenters suggested reducing the scope of this proposed criterion to either divide out the requirements into separate certification criteria or to only require the minimum functionalities needed to achieve the corresponding proposed e-prescribing objective for Stage 3 of the EHR Incentive Programs (80 FR 16747).

Response. In finalizing the e-prescribing criterion, we considered whether the proposed functionality would help achieve interoperability between health IT systems and would align with the goals and objectives described in the "Federal Health IT Strategic Plan."⁵⁷ The reasons for the finalized e-prescribing criterion and its included functionality are described below in response to comments.

Comments. A number of commenters supported the additional NCPDP SCRIPT v10.6 transactions we proposed to require for testing and certification to this criterion, and believed the additional requirement would facilitate bidirectional prescriber-pharmacist communications and comprehensive medication management. A number of commenters were concerned about the variable adoption and use of the additional NDPCP SCRIPT v10.6 transactions that were proposed. A few commenters were concerned with the interruptive nature of real-time messaging alerts and suggested that they be batch-processed to a team rather than a single provider for viewing. One commenter suggested that we verify the correct official names of the proposed NCPDP SCRIPT v10.6 transactions. Regarding the medication history transactions, a few commenters noted that many EHRs support additional means of retrieving medication history that can offer advantages to the NCPDP medication history transactions (e.g., HL7, proprietary third party integration, direct connection with third party payers).

Response. We thank commenters for their support of the proposal. Providers that prescribe or dispense Medicare Part D drugs using electronic transmission of prescriptions are required to comply with the standards that CMS has adopted under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. CMS adopted NCPDP SCRIPT v10.6 for Part D e-prescribing in the 2013 Physician Fee Schedule final rule (77 FR 69330–69331) effective November 1, 2013, including the following transactions which we also proposed to

require for 2015 Edition testing and certification:

- New prescription transaction;
- Prescription change request transaction;
- Prescription change response transaction;
- Refill prescription request transaction;
- Refill prescription response transaction;
- Cancel prescription request transaction;
- Cancel prescription response transaction; and
- Fill status notification.

We believe that providers that are e-prescribing under Part D should have already adopted NCPDP SCRIPT v10.6 for these transactions as required effective November 1, 2013. Further, by requiring these transactions as part of certification, we are supporting the use of additional NDPCP SCRIPT v10.6 transactions in a standardized way.

Comments. Some commenters also noted support for the medication history transaction request and response transactions, and other commenters noted that both pharmacy and EHR systems have widely adopted the medication history transactions.

Response. As stated in the Proposed Rule, we believe that all the above proposed transactions can facilitate prescriber and pharmacist communications that advance better care for patients and improve patient safety. Therefore, in support of these goals and to harmonize with CMS' Part D requirements, we have finalized our proposal to require that certified health IT systems enable a user to prescribe, send, and respond to the following NCPDP SCRIPT v10.6 transactions for certification to the 2015 Edition e-prescribing criterion:

- New prescription transaction (NEWRX);
- Prescription change request transaction (RXCHG);
- Prescription change response transaction (CHGRES);
- Refill prescription request transaction (REFREQ);
- Refill prescription response transaction (REFRES);
- Cancel prescription request transaction (CANRX);
- Cancel prescription response transaction (CANRES);
- Fill status notification (RXFILL);
- Medication history request transaction (RXHREQ); and
- Medication history response transaction (RXHRES).

We have confirmed the official name of these transactions with NCPDP. We note that the requirements we have

⁵⁶ <http://www.ncdp.org/NCPDP/media/pdf/SCRIPTImplementationRecommendationsV1-29.pdf>.

⁵⁷ http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

finalized outline the capabilities that certified health IT must be able to support, and do not require providers to use these functionalities when e-prescribing. The requirements of providers and prescribers for e-prescribing are specified by other programs, such as the implementation of the Medicare Modernization Act and the EHR Incentive Programs. We also note that there are other standards and services available for requesting and receiving medication history information. Our adoption of the NCPDP SCRIPT v10.6 medication history request and response transactions is consistent with a standard that commenters agreed is widely used and—as above stated—has been adopted by the health care industry. Our adoption of these requirements does not preclude developers from incorporating and using technology standards or services not required by our regulation in their health IT products.

Regarding how message notifications are presented to health IT users, we believe this is a design feature that should be left to providers and health IT developers to determine, including whether batch notification is preferable to real-time messaging alerts.

Comments. Some commenters suggested that it was premature to require end-to-end bidirectional testing because they believed pharmacy systems may not support the transactions. Commenters also asked for clarification on how certified health IT would be tested to demonstrate end-to-end bidirectional messaging. A number of commenters suggested ONC consider deeming Surescripts certification to count towards meeting the requirements of ONC's Health IT Certification Program. A few commenters also were concerned about the differences between Surescripts and testing and certification requirements under the ONC Health IT Certification Program.

Response. ONC published a notice in the **Federal Register** (80 FR 32477) that restated our commitment to work with the health IT industry towards a more streamlined health IT testing and certification system. This notice addressed a flexibility included in the ONC Health IT Certification Program that allows the National Coordinator to approve test procedures, test tools, and test data developed by non-governmental entities for testing efficiencies in the ONC Health IT Certification Program. A person or entity may submit a test procedure or test tool (which includes test data) to the National Coordinator for Health IT to be considered for approval and use by

NVLAP accredited testing laboratories. We strongly encourage persons or entities to submit such test procedures, test tools, and test data to us if they believe such procedures, tools, and data could be used to meet certification criteria and testing approval requirements, including those for e-prescribing functionalities. Given our policy that permits any person or entity to submit test procedures, test tools, and test data for approval and use under the ONC Health IT Certification Program, we encourage stakeholders to review the **Federal Register** notice and submit test procedures, test tools, and test data for approval by the National Coordinator in accordance with the instructions outlined in the notice.⁵⁸

We look forward to testing tools that allow pharmacy communications to either be simulated or sent by a pharmacy system that has agreed to participate in the ONC Health IT Certification Program as a pilot test system that is able to emulate real-life e-prescribing scenarios. We note that we intend to analyze any differences between our requirements for testing and certification to this certification criterion and other industry certification programs for e-prescribing to determine opportunities for alignment. However, we note that industry certification programs may address a different use case and potentially test more functionality than required by this certification criterion.

Comments. A number of commenters were concerned with the limitation of the NCPDP Structured and Codified Sig Format Implementation Guide v1.2 that limits the structured and codified Sig text element to 140 characters, and noted that it could hinder the ability to transmit complex dosing instructions (e.g. tapers). Commenters noted that a later version of the NCPDP SCRIPT Standard Implementation Guide expands this text element length to 1,000 characters, but recommended that we not adopt this version until CMS has adopted a later version as a requirement for part of Part D e-prescribing. Commenters were also concerned that the NCPDP Structured and Codified Sig Format v1.2 is not widely implemented and needs more testing. A number of commenters noted NCPDP is in the process of updating the NCPDP SCRIPT Implementation Recommendations to reflect updates in guidance on implementation of the most common Sig instructions. Some commenters also

noted that there are newer versions to the NCPDP SCRIPT Implementation Recommendations than v1.29. These commenters were concerned that guidance on implementing the most common Sig instructions is still evolving and suggested that we wait until there is more implementation experience with using the NCPDP Structured and Codified Sig Format v1.2 and later versions before considering inclusion in a certification criterion. A number of commenters supported the Sig segment for the indication for the medication to be documented in SNOMED CT[®] to assist the pharmacist with medication counseling and care coordination, whether or not ONC were to adopt the full NCPDP Structured and Codified Sig Format v1.2.

Response. We thank commenters for their detailed comments and recommendations. We acknowledge the limitations of the 140 character structured and codified Sig, and the concerns with low implementation of the NCPDP SCRIPT Structured and Codified Sig Format v1.2 and later versions. In light of our decision to focus on interoperability and considerations about the maturity of standards, we have not finalized the proposal to require a Health IT Module certified to this criterion to enable a user to enter, receive, and transmit codified Sig instructions in a structured format. While we continue to believe that e-prescribed medication instructions should be transmitted in a structured format for improved patient safety and for clearer communication of the prescribing information as intended by the prescriber, we do not believe a standard is ready for adoption at this point in time. We will continue to monitor CMS's requirements for Part D e-prescribing, and may reconsider this stance for future rulemaking based on newer versions of the NCPDP SCRIPT Standard Implementation Guide that may provide implementation improvements.

While we are not adopting the NCPDP SCRIPT Structured and Codified Sig Format v1.2 in its entirety, we agree with commenters on the potential benefits of a field that captures the reason for the prescription. This information has value for care coordination between prescribers, pharmacists, and care team members. NCPDP SCRIPT v10.6 supports the exchange of the reason for the prescription in a few ways, including (1) medication-associated diagnosis using diagnosis elements in the DRU (Drug Segment) and (2) medication indication using the indication elements in the SIG (Structured Sig Segment).

⁵⁸ <https://www.federalregister.gov/articles/2015/06/09/2015-13510/acceptance-and-approval-of-non-governmental-developed-test-procedures-test-tools-and-test-data-for>.

For the first method, NCPDP SCRIPT v10.6 supports use of ICD-9-CM codes or ICD-10-CM codes with an additional qualifier. However, the standard does not permit the medication-associated diagnosis to be exchanged using SNOMED CT® codes until version 2013011 and later. We continue to support SNOMED CT® as the vocabulary code set for clinical diagnoses. Despite the limitation of NCPDP SCRIPT v10.6 regarding exchange of SNOMED CT® codes for medication-associated diagnoses, e-prescribing transactions that include the reason for the prescription support patient safety and align with initiatives underway at HHS.⁵⁹ While the use of ICD-10-CM for medication-associated diagnoses is not ideal, the value of requiring a field for medication-associated diagnoses in accordance with NCPDP SCRIPT v10.6 outweighs the limitations of that version of the standard. We will consider requiring certification for the medication-associated diagnosis using SNOMED CT® codes in a future version of this certification criterion if we adopt a version of NCPDP SCRIPT that can support medication-associated diagnoses using SNOMED CT® codes.

The second method described above (medication indication using indication elements in the SIG) does support the use of SNOMED CT® vocabulary. In order to implement the indication elements in the SIG, developers would need to implement at least a subset of the structured and codified Sig format component composites that represent the most common Sig instructions as described in the SCRIPT Implementation Recommendations Version 1.29⁶⁰ and later. As we have not adopted the proposal to require a Health IT Module certified to this criterion to enable a user to enter, receive, and transmit codified Sig instructions in a structured format, implementation of this second method would depend on whether the developer voluntarily chooses to implement Structured and Codified Sig Format v1.2.

Given the options discussed above, we have finalized a requirement that requires a Health IT Module to enable a user to receive and transmit the reason for the prescription using the diagnosis elements in the DRU Segment. This requirement would apply to the new, change request and response, cancel

request and response, refill request and response, fill status, and medication history request and response NCPDP SCRIPT v10.6 transactions that we have required in this criterion (see discussion above). Again, we note that this requirement would only apply to the capability that a certified Health IT Module certified to this criterion has to demonstrate, not that a provider is required to populate the field for reason for the prescription when e-prescribing. For the first method described above, we note that with compliance deadline of October 1, 2015, for use of ICD-10-CM and the effective date of this final rule, we intend to test compliance with ICD-10-CM for the purposes of testing and certification under the ONC Health IT Certification Program.

We are also including an optional provision that would test a Health IT Module's ability to enable a user to receive and transmit the reason for the prescription using the indication elements in the SIG Segment for those developers that may have voluntarily chosen to implement the Structured and Codified Sig Format v1.2.

Comments. Commenters were generally supportive of improving patient safety through use of the metric standard for dosing, but recommended that this requirement only apply to oral liquid medications. A number of commenters noted that the dose quantity for non-oral, non-liquid medications may not be representable using metric units (e.g., number of puffs for inhalers, number of drops for ear and eye drops, "thin film" for topic creams and ointments). There was some concern that pharmacies may translate metric prescribing instructions into more "patient friendly" instructions (such as translating from mL to "spoonfuls") that could lead to patient dosing concerns. Commenters were also supportive of the proposal to require the use of standard conventions for leading zeroes and decimals (i.e., a leading zero is always inserted before the decimal point for amounts less than one, as well as not allowing trailing zeroes after a decimal point).

Response. We thank commenters for their support of the proposal, and for clarifying the issue about non-metric dose quantities. Given this input and support, we have finalized the requirement that a Health IT Module be capable of limiting a user's ability to electronically prescribe *oral, liquid medications* in only metric standard units of mL (i.e., cc units will not be allowed for certification). A Health IT Module certified to this criterion would also be required to always insert leading zeroes before the decimal point for

amounts less than one when a user electronically prescribes all medications, as well as not allow trailing zeroes after a decimal point. Stakeholder feedback has indicated that medication labels will contain dosing instructions in the metric standard if the prescriber doses in the metric standard. Along with federal partners (including the FDA and CDC),⁶¹ we encourage pharmacies to ensure the labels maintain the metric standard for dosing instructions. Guidance already exists encouraging this as a best practice for medication labeling.⁶² We understand that industry best practices also promote the provision of a metric dosing device along with oral liquid medications.⁶³ Last, for purposes of patient safety, we would also encourage health IT developers to implement industry recommendations around the use of "tall man lettering" to differentiate between drug names that are similar and commonly confused.⁶⁴

Comments. Commenters were supportive of the proposal to adopt the February 2, 2015, monthly version of RxNorm. A few commenters suggested that we adopt this version at a minimum, but allow implementation of later versions.

Response. We thank commenters for their support and have adopted the September 8, 2015 monthly version of RxNorm.⁶⁵ As we finalized in the 2014 Edition final rule (77 FR 54170), we remind stakeholders that our policy for "minimum standards" code sets permits the adoption of newer versions of the adopted baseline version minimum standards code sets for purposes of certification unless the Secretary specifically prohibits the use of a newer version (see § 170.555 and 77 FR 54268). We agree with stakeholders that the adoption of newer versions of RxNorm can improve interoperability and health IT implementation.

Comments. A few commenters noted there is a need for standards for e-prescribing of controlled substances (EPCS). One commenter suggested that a standard for prior authorization (ePA) prescribing transactions is needed.

Response. We thank commenters for these suggestions, but note that these

⁶¹ http://www.cdc.gov/MedicationSafety/protect/protect_initiative.html#MedicationErrors.

⁶² <http://www.ncdp.org/NCPDP/media/pdf/wp/DosingDesignations-OralLiquid-MedicationLabels.pdf>.

⁶³ <http://www.ncdp.org/NCPDP/media/pdf/wp/DosingDesignations-OralLiquid-MedicationLabels.pdf>.

⁶⁴ <http://www.ismp.org/Tools/tallmanletters.pdf>.

⁶⁵ We refer readers to section III.A.2.c ("Minimum Standards" Code Sets) for a more detailed discussion of our adoption of the September 8, 2015 monthly version of RxNorm.

⁵⁹ <http://chainonline.org/research-tools/improving-hit-prescribing-safety/>.

⁶⁰ <http://www.ncdp.org/NCPDP/media/pdf/SCRIPTImplementationRecommendationsV1-29.pdf>.

comments are outside the scope of this criterion as proposed.

- *Common Clinical Data Set Summary Record—Create; and Common Clinical Data Set Summary Record—Receive*

2015 Edition Health IT Certification Criterion

§ 170.315(b)(4) (Common Clinical Data Set summary record—create)

2015 Edition Health IT Certification Criterion

§ 170.315(b)(5) (Common Clinical Data Set summary record—receive)

In the Proposed Rule under the proposed 2015 Edition “transitions of care” certification criterion, we solicited comment on whether we should adopt and make available for testing and certification a separate certification criterion focused on the capability to create a summary record formatted to the C-CDA Release 2.0 with or without the ability to meet the requirements of the Common Clinical Data Set definition.

Comments. Comments generally supported the proposal to adopt a separate certification criterion for the ability of a Health IT Module to create a summary care record formatted to the C-CDA standard. A few commenters suggested that this certification criterion would only be valuable if the Common Clinical Data Set was included as well. Similar to the comments received for the “ToC” criterion summarized previously in this section of the preamble, commenters were concerned that C-CDA documents formatted to Release 2.0 would not provide compatibility with C-CDA Release 1.1. These commenters recommended that this certification criterion should require creation of C-CDAs consistent with C-CDA Release 2.1.

Response. We agree with commenters that this criterion will be valuable if it includes the capability to create a C-CDA with the Common Clinical Data Set. This criterion may also be valuable and less burdensome for health IT developers that design technology for other programs and settings outside of the EHR Incentive Programs that would like to require or offer functionality for the creation of C-CDA documents without the other requirements of the 2015 Edition “transitions of care” criterion (e.g., transport requirements). These programs and settings may find value for providers to create a summary care record or transition of care document in accordance with the C-CDA standard and with the Common Clinical Data Set. For example, existing

CMS programs point to the use of technology certified to create C-CDA documents with the Common Clinical Data Set, including for chronic care management services in the CY 2016 Physician Fee Schedule final rule (80 FR 41796). CMS programs also encourage the use of certified health IT for various settings and purposes.⁶⁶ Accordingly, we have adopted a new 2015 Edition “Common Clinical Data Set summary record—create” certification criterion to support this and other use cases. We have also adopted a similar criterion that would support receipt of health information exchanged in accordance with this functionality (Common Clinical Data Set summary record—receive” certification criterion).

Common Clinical Data Set Summary Record—Create

This new criterion would require a Health IT Module enable a user to create a transition of care/referral summary formatted in accordance with C-CDA Release 2.1 and that includes, at a minimum, the Common Clinical Data Set and patient matching data. For the same reasons described in the “ToC” certification criterion above, the patient match data represent a first step forward to improving the quality of data included in an outbound summary care record to improve patient matching. Please refer to our decision to adopt C-CDA Release 2.1 for all certification criteria that reference C-CDA standard creation in the 2015 Edition as described further in the preamble for the “ToC” certification criterion. Consistent with our decision for the “ToC,” “clinical information reconciliation and incorporation,” and “C-CDA creation performance” criteria described elsewhere in this section of the preamble, this certification criterion references the C-CDA Release 2.1 CCD, Referral Note, and (for inpatient settings only) Discharge Summary document templates for this certification criterion.

We have also included the encounter diagnoses (with either the September 2015 Release of the US Edition of SNOMED CT® or ICD-10 codes), cognitive status, functional status, reason for referral (ambulatory only), referring or transitioning provider’s name and office contact information (ambulatory only), and discharge instructions (inpatient only) which are contained in the “transitions of care” criterion. This data has value for

providing additional context and information for providers to make care decisions when receiving and sending transition of care/referral summary documents. As noted above, certain CMS programs have required or encouraged that this data be transmitted between care settings. Inclusion of this data will promote consistency for transitions of care across care settings and highlight ongoing efforts to develop standards for representing this data electronically.

Common Clinical Data Set Summary Record—Receive

In addition to adopting a new certification criterion for “Common Clinical Data Set summary record—create,” we have also adopted a complementary certification criterion focused on the receipt and proper processing of a transition of care/referral summary formatted to C-CDA and with the Common Clinical Data Set. Our goal is to ensure that when a C-CDA document is created consistent with the “Common Clinical Data Set summary record—create” certification criterion that the receiving system can properly process the information for informing care coordination. This has value for stakeholders such as providers who may be participating in other programs that require the use of the “Common Clinical Data Set summary record—create” functionality as well as registries that may be recipients of this information. As stated in the Federal Health IT Strategic Plan, core technical standards form the foundation for interoperability, and systems that send and receive information in these common standards will help ensure the meaning of information is consistently understood.⁶⁷

In order to ensure the receiving system correctly processes the C-CDA document, we will test that a system can properly validate the information in accordance with the same requirements of the “ToC” criterion (e.g., parse, detect and notify users of errors, identify valid document templates and process data elements, and correctly interpret empty sections and null combinations and be able to display a human readable format that contains the information in the received C-CDA document in accordance with the C-CDA standard). These methods mirror those in the “ToC” criterion and will provide baseline assurance that a receiving system can properly process the C-CDA document as together they verify that the Health IT Module is correctly

⁶⁶ We refer readers to section IV.B.4 (“Referencing the ONC Health IT Certification Program”) of this preamble for discussion of these programs and associated rulemakings.

⁶⁷ http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf.

interpreting the received C-CDA document information.

Consistent with our decision for the “ToC” and “clinical information reconciliation and incorporation” certification criteria described above, we have required certification to the C-CDA Releases 1.1 and 2.1 CCD, Referral Note, and (for inpatient settings only) Discharge Summary document templates for this certification criterion. As previously discussed, while C-CDA Release 2.1 largely promotes compatibility with C-CDA Release 1.1, receiving systems may have to perform additional processing to ensure Release 1.1 conformance with Release 2.0. We have included a requirement that Health IT Modules be able to receive C-CDA documents with the encounter diagnoses (with either the September 2015 Release of the U.S. Edition of SNOMED CT® or ICD-10-CM codes), cognitive status, functional status, reason for referral (ambulatory only), referring or transitioning provider’s name and office contact information (ambulatory only), and discharge instructions (inpatient only) for the same reasons we have included these data in the “Common Clinical Data Set summary record—create” criterion described above.

We have also included the “section views” capability from the “ToC” certification criterion to ensure that Health IT Modules certified to this certification criterion will be able to extract and allow for individual display each section (and the accompanying document header information (*i.e.*, metadata)) that was included in a transition of care/referral summary received and formatted in accordance with C-CDA Releases 1.1 and 2.1. This will allow a user to select and just view the relevant sections without having to navigate a potentially length C-CDA document.

- *Data Export*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(6) (Data export)

We proposed to adopt a 2015 Edition “data portability” certification criterion that was revised in comparison to the 2014 Edition “data portability” certification criterion (§ 170.314(b)(7)). Similar to the 2014 Edition version, we proposed to include the 2015 Edition “data portability” criterion in the Base EHR definition (*i.e.*, the 2015 Base EHR definition). To address feedback from health IT developers and providers on the 2014 Edition certification criterion, the proposed “data portability” certification criterion at § 170.315(b)(6)

focused on specific capabilities that would give providers easy access and an easy ability to export clinical data about their patients for use in a different health information technology or a third party system for the purpose of their choosing. We emphasized that this capability would need to be user-focused and user-driven. We proposed to require that a user be able to configure a Health IT Module to create an export summary for a given patient or set of export summaries for as many patients selected and that these export summaries be able to be created according to certain document-template types included in the C-CDA Release 2.0. We proposed to require the Common Clinical Data Set as the minimum data that a Health IT Module must be capable of including in an export summary, in addition to encounter diagnoses (according to the standard specified in § 170.207(i) (ICD-10-CM) or, at a minimum, the version of the standard at § 170.207(a)(4) (September 2014 Release of the U.S. Edition of SNOMED CT®), cognitive status, functional status, reason for referral and the referring or transitioning provider’s name and office contact information, and discharge instructions for the inpatient setting. We proposed to require that a user would need to be able to be able to configure the technology to set the time period within which data would be used to create the export summary or summaries, and that this must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date. We proposed to require that a user would need to be able to configure the technology to create an export summary or summaries based on specific user selected events listed in the Proposed Rule. We proposed to require that a user would need to be able to configure and set the storage location to which the export summary or export summaries were intended to be saved.

Comments. Many commenters expressed support of the concept of “data portability.” Many commenters also requested that we clarify the purpose of data portability and provide related use cases to distinguish “data portability” from the transition of care certification criterion. Some commenters also suggested renaming the criterion to better describe its intended use. One commenter noted the “ambulatory only” requirement included in the criterion seemed to be confusing data portability with transition of care.

Response. We appreciate commenters’ support of the concept of data

portability and the proposed certification criterion. To provide additional clarity, we have decided to simply name the adopted certification criterion in this final rule “data export.”

This certification criterion’s purpose is to enable a user to export clinical data from health IT for one patient, a set of patients, or a subset of that set of patients. The functionality included in the criterion is intended to support a range of uses determined by a user and it was not our intention to prescribe or imply particular uses for this functionality. We also note that this functionality is not intended to and may not be sufficient to accomplish a full migration from one product to another without additional intervention because of the scope of this criterion. Specifically, the data and document templates specified in this criterion would not likely support a full migration, which could include administrative data such as billing information. The criterion’s functionality could, however, support the migration of clinical data between health IT systems and can play a role in expediting such an activity if so determined by the user.

The “inpatient only” and “ambulatory only” portions of the criterion that require referral and discharge information, respectively, were part of the scope of 2014 Edition “data portability” certification criterion, are part of the transition of care criterion, and are also referenced in by the “VDT” criterion. As such, we see no compelling reason to change this criterion’s scope and have adopted the criterion with these distinctions and data.

Comments. Some commenters supported requiring all of the proposed C-CDA document templates. Other commenters stated that the number of document templates should be limited. Some commenters had recommendations on alternative vocabularies to include in the C-CDA.

Response. Consistent with other responses provided in this final rule, this certification criterion requires conformance to the C-CDA R2.1. In consideration of comments received on the Proposed Rule, we have limited the C-CDA document template scope for this criterion to the CCD document template. We note that the vocabularies used by the C-CDA R2.1 are defined through the Standards Developing Organization (SDO) process and we do not seek to change that approach via this rulemaking (*i.e.*, we adopt the C-CDA R2.1 as published). We note that we have adopted this criterion with the proposed inclusion of the Common

Clinical Data Set and other specified data, including the updated minimum standards code sets we discuss in section III.A.2.c (“Minimum Standards” Code Sets) of this preamble.

Comments. One commenter stated that when a note is signed or an order is placed does not necessarily indicate that all relevant documentation is ready for export as the provider may enter more information in the record or a result could come back from a laboratory order. The commenter stated that this could result in incomplete data being exported. Another commenter stated that there should be an affirmative action by the user clearly indicating the intent to initiate a data export. A commenter suggested removal of the requirements related to event configuration, stating there was no clear use case. Commenters also stated that the dates in the “timeframe configuration” were unclear and sought clarification on whether it was an admission date, an encounter date, the date the data was entered in the system or some other date. One commenter recommended that providers should have access to the full set of data included in the certified health IT for the entire period covered by a provider’s contract. The HITSC stated in written advice to the National Coordinator that the “trigger conditions” were not appropriate and went beyond what it believed the policy goals for this criterion.⁶⁸

Response. In consideration of comments, we have not finalized the requirement to permit a user to configure a data export based on signing a note or placing an order. We believe that a time-based approach as the baseline scope for this certification criterion is the most appropriate, consistent with our policy goals, and helps balance user functionality required for the purposes of certification with developer burden. In that regard, by finalizing a time-based approach, we have determined that this final certification criterion can be more simply described by combining the proposed “timeframe” and “event” configurations into one provision.

We have also not adopted the proposed time requirement that technology would need to include the ability to set a date at least three years into the past from the current date. We have determined that we could not properly test and certify to such a requirement. We acknowledge that some Health IT Modules presented for

certification, particularly in 2016, will not have access to three or even one year’s worth of patient health information that is conformant to the standards requirements of this criterion. A health IT developer’s and Health IT Module’s access to such health information, and the quality of such health information, will also likely vary considerably based on the customers (providers) it serves. This would further complicate testing and certification, and potentially place certain health IT developers and products at a disadvantage. Therefore, we have not adopted this proposed requirement.

We have finalized as part of this criterion a specific capability that expresses time-based configuration requirements. This first portion of this part of the criterion expresses that a user must be able to configure a time period within which data would be used to create export summaries, which must include the ability to express a start and end date range. The second portion of this part of the criterion expresses three time-based actions/configurations a user must be able to complete based on the date range they have specified. A user would need to be able to: (1) Create export summaries in real-time (*i.e.*, on demand); (2) configure technology to create such summaries based on a relative date and time (*e.g.*, generate a set of export summaries from the prior month on the first of every month); and (3) configure technology to create such summaries based on a specific date and time (*e.g.*, generate a set of export summaries with a date range between January 1, 2015 and March 31, 2015 on April 1, 2015 at 1:00AM EDT). We reiterate that a Health IT Module will need to support the user’s ability to select and configure those dates and times.

Comments. One commenter requested that the “file location” be a Direct address or an external location in an HIE or some other system.

Response. For the purposes of certification, we clarify that a Health IT Module must, at a minimum, permit a user to select a local or network storage location. We have intentionally left the specific transport method (*e.g.*, sending to a Direct email address) or further product integration (*e.g.*, routing the export to a web service, web service or integration engine) to the discretion of the health IT developer and its customers.

Comments. Commenters expressed concern that privacy and security issues may arise when data is exported. Some commenters suggested that the criterion should require an ability to limit the users that would be permitted to

execute the data export functionality, contending that limiting the users could address potential performance issues that may result when executing this functionality as well as issues related to use access or misuse.

Response. We thank commenters for raising these issues and have modified this criterion in response. We agree that this certification criterion could benefit from requiring health IT to include a way to limit the (type of) users that would be able to access and initiate data export functions. Thus, consistent with other certification criteria that include functionality to place restrictions on the (type of) users that may execute this functionality, we have adopted corresponding language in this final criterion. However, we emphasize for stakeholders this additional “limiting” functionality on the type of users that may execute the data export functionality is intended to be used by and at the discretion of the provider organization implementing the technology. In other words, this functionality cannot be used by health IT developers as an implicit way to thwart or moot the overarching user-driven aspect of this certification criterion.

- *Data Segmentation for Privacy*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(7) (Data segmentation for privacy—send)

2015 Edition Health IT Certification Criterion
§ 170.315(b)(8) (Data segmentation for privacy—receive)

We proposed to adopt two new 2015 Edition certification criteria referred to as “data segmentation for privacy (DS4P)—send” and data segmentation for privacy (DS4P)—receive.” These criteria were not proposed to be in scope for the EHR Incentive Programs. Rather, they were proposed to be available for health IT developers and other programs. The proposed certification criteria focused on technical capabilities to apply and recognize security labels (*i.e.*, privacy metadata tags) to a patient’s health record. We noted in the Proposed Rule that the technical capabilities to do so would enable a sending provider’s technology to tag a patient’s record such that recipient of such a record (if such recipient had also implemented the technology) would be able to recognize that the patient’s record was “sensitive” and needed special protection under federal or state privacy law. For example, DS4P was piloted to support the exchange of health information

⁶⁸ https://www.healthit.gov/FACAS/sites/faca/files/HITSC_Certification_NPRM_TSSWG_Comments_2015-05-20.pdf.

covered by 42 CFR part 2 (“Part 2”), which are federal regulations implementing the law protecting confidentiality of, and restricting access, to substance abuse related patient records.

We proposed to adopt the DS4P standard as outlined in the HL7 Version 3 Implementation Guide: DS4P, Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata.⁶⁹ The standard describes the technical means to apply security labels to a health record and data may be tagged at the document-level, the section-level, or individual data element-level. The DS4P standard also provides a means to express obligations and disclosure restrictions that may exist for the data. The DS4P standard does not enforce privacy laws or alter privacy laws. A healthcare provider is still responsible for ensuring that use, access, or disclosure of the sensitive health information complies with relevant state and federal law. DS4P supports that compliance in an electronic health environment and is a means for providers to electronically flag certain pieces of data that may be subject to those laws. Importantly, the DS4P standard is “law-agnostic” and not restricted to Part 2 data. It may be implemented to support other data exchange environments in which compliance with state or federal legal frameworks require sensitive health information to be tagged and segmented.

Comments. In general, most commenters recognized the value in complying with laws that require protecting sensitive health information. However, we received comments both expressing support and opposition to adopting the proposed certification criteria at this time. Commenters in support of the DS4P certification criteria and proposed standard pointed out the standard was the best currently available option for protecting sensitive health information and allows behavioral health, substance abuse, and other data to be available at the point of care. Commenters cited teenagers, victims of intimate partner violence, and patients with behavioral health or substance abuse conditions as particularly vulnerable populations that would benefit from the ability to exchange sensitive health information electronically. Several commentators pointed out that, while we limited segmentation to document-level tagging in the Proposed Rule preamble, we did

not do so in the proposed regulation text.

Commenters that expressed opposition to the DS4P certification criteria and proposed standard stated that the standard was immature and not widely adopted. The commenters expressed concern that segmentation can lead to incomplete records and that receiving systems may not know how to handle the DS4P tagged data, which could lead to incomplete records that may subsequently contribute to patient safety issues. Several comments stated that DS4P has only been piloted with Part 2 data. One commenter requested clarification on how a sending system will know if a receiving system supports DS4P. Commenters also requested guidance on how to visualize in the system that data may be incomplete or what workflows should be used when segmented data is received. Several commentators requested that we consider the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework Volume 4—National Extensions—Section 3.1 Data Segmentation for Privacy (DS4P)⁷⁰ as an alternative to the DS4P IG.

Response. We appreciate the thoughtful comments submitted on the proposed criteria. Notably, with respect to the comments we received that expressed opposition to the DS4P standard our analysis of the comments indicates that commenters were more concerned with the complexity of the privacy law landscape than they were about the technology itself. In this regard, the vast majority of comments focused on policy-related questions such as the likelihood that specialized privacy laws might create “holes” in the data. Additionally, we received no comments that provided substantive technical criticisms of the DS4P standard.

In reference to the DS4P standard’s maturity, we note that it is considered a “normative” standard from the HL7 perspective—a status which requires substantially higher HL7 membership participation compared to a Draft Standard for Trial Use (DSTU) status. While we recognize that to date the standard has not been widely adopted, it has been used with Part 2 data and other sensitive health information by the Substance Abuse and Mental Health Services Administration (SAMHSA), the U.S. Department of Veterans Affairs (VA), and private companies.

In consideration of the comments we received and several of HHS’ overarching policy goals (enabling

interoperability, supporting delivery system reform, reducing health disparities, and supporting privacy compliance), we have adopted the proposed DS4P criteria. We note that these criteria are not part of the 2015 Edition Base EHR definition, are not required in the certification program policies for health IT developers to seek certification to, and are not required for providers to participate in the EHR Incentive Programs. As we have stated, DS4P enables sensitive health information to be exchanged electronically and we strongly encourage health IT developers to include DS4P functionality and pursue certification of their products to these criteria in order to help support their users’ compliance with relevant state and federal privacy laws that protect sensitive health information.

We agree with commenters that we should explicitly state that document-level tagging is the scope required for certification and have made this modification to criteria. We have also clearly indicated in the DS4P-receive criterion that the ability to receive a summary record in accordance with the C—CDA R2.1 is required. This was inadvertently omitted from the criterion’s proposed regulation text, but was referenced in the DS4P-send criterion.

In response to the broader comments that were critical of the notion of DS4P, we reiterate that DS4P is a technical standard that helps healthcare providers comply the laws applicable to them. As such, healthcare providers should already have processes and workflows to address their existing compliance obligations. The DS4P standard does not itself create incomplete records. Under existing law patients already have the right to prevent re-disclosure of certain types of data by withholding consent to its disclosure or to place restrictions on its re-disclosure. DS4P allows providers to tag data as sensitive and express re-disclosure restrictions and other obligations in an electronic form. DS4P does not determine whether a segmentation obligation exists legally or what that legal obligation means to the recipient. Instead, DS4P allows for tagging and exchange of health information that has already been determined to be sensitive and in need of special protections. In the absence of DS4P, this specially protected data may still be exchanged, if consent is given for disclosure, by fax or mail, but these methods may make the data unavailable in electronic form in the receiving provider’s EHR.

We recognize that the current privacy law landscape is complex. Despite the

⁶⁹ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354 Completed Normative Ballot in January 2014 and was successfully reconciled in February 2014. HL7 approved the final standard for publication and ANSI approved in May 2014.

⁷⁰ http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf.

complexities of the privacy law landscape, we believe now is the time to support a standard that allows for increased protection for individuals with sensitive health conditions and enables sensitive health information to flow more freely to authorized recipients. Over 43 million Americans ages 18 and up have some form of mental illness.⁷¹ As stated before, providers already have workflows to care for individuals with these and other sensitive health conditions. DS4P allows providers the ability to move away from fax-and-paper information exchange into interoperable exchange of sensitive health information. Oftentimes, individuals with sensitive health conditions require coordinated care that is not possible if sensitive health data cannot be exchanged. Additionally, the technical ability to segment data supports the Precision Medicine Initiative⁷² and delivery system reform⁷³ where those initiatives depend on making computable individual's choices about disclosure of their data.

The current DS4P standard does not have a service discovery mechanism to determine if a potential recipient is able to receive a tagged document. We expect that providers will have to determine the receiving capabilities of their exchange partners, similar to how they have to work with their exchange partners today when they are manually exchanging sensitive health information via fax. Additionally, the DS4P standard contains a human-readable text block that will render in the recipients system—putting the human healthcare user on notice that they are viewing sensitive health information, allowing them to take appropriate actions in their system manually.

We are not aware of implementations that have used the IHE National Extensions for Data Segmentation for Privacy and do not agree with permitting it as an alternative approach to DS4P for the purposes of certification at this time.

- *Care Plan*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(9) (Care plan)

We proposed to adopt a new 2015 Edition certification criterion that

would require a Health IT Module to enable a user to record, change, access, create and receive care plan information in accordance with the Care Plan document template in the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes.⁷⁴ We explained that the C–CDA Release 2.0 contains a Care Plan document template that provides a structured format for documenting information such as the goals, health concerns, health status evaluations and outcomes, and interventions. We emphasized that the Care Plan document template is distinct from the “Plan of Care Section” in previous versions of the C–CDA, stating that the Care Plan document template represents the synthesis of multiple plans of care (for treatment) for a patient, whereas the Plan of Care Section represented one provider's plan of care (for treatment). The Proposed Rule noted that the C–CDA Release 2.0 had renamed the previous “Plan of Care Section” as the “Plan of Treatment Section (V2)” for clarity. We sought comment on whether we should require for certification to this criterion certain “Sections” that are currently deemed optional as part of the Care Plan document template for certification to this criterion, namely the “Health Status Evaluations and Outcomes Section” and “Interventions Section (V2).”

Comments. Commenters were supportive of the proposal to adopt a new voluntary “care plan” criterion. The commenters stated that the Care Plan document template supports broader information about the patient, including education, physical therapy/range of motion, and social interventions not commonly found in other parts of the C–CDA standard. A few commenters stated that the C–CDA Release 2.0 Care Plan document template only represents a “snapshot in time,” rather than a dynamic, longitudinal shared care plan. Some commenters expressed concern that this document template is new to C–CDA Release 2.0 and suggested that there was no implementation experience. Other commenters stated that clinician input was factored into the development of the Care Plan document template and that there have been pilots through the S&I Framework Longitudinal Coordination of Care Initiative.⁷⁵ Commenters suggested that the inclusion of the Care Plan document template in certification would provide

a glide path for adoption of EHRs by home health care and hospice providers.

Response. We thank commenters for their feedback. As stated in the Proposed Rule (80 FR 16842), we believe the Care Plan document template has value for improving coordination of care and provides a structured format for documenting information such as goals, health concerns, health status evaluations, and interventions. It represents a consensus-based approach and is the best standard available today for capturing and sharing care plan information. The document template has also been demonstrated through pilots in the S&I Framework. As such, we have adopted this criterion. To note, we have adopted the C–CDA Release 2.1 standard for this certification criterion for consistency with our approach to the C–CDA in this final rule and for the same substantive reasons discussed earlier in this preamble under the “ToC” certification criterion.

Comments. A few commenters suggested that it was not necessary to adopt this certification criterion because other proposed criteria also reference the C–CDA standard and Care Plan template.

Response. As described in more detail in this preamble for the other certification criteria we have adopted that reference the C–CDA standard (e.g., “ToC,” “data export,” and “Consolidated CDA creation performance”), we have adopted reduced requirements for C–CDA Release 2.1 document template conformance per the use case(s) served by each certification criterion. As such, the “ToC,” “data export,” “clinical information reconciliation,” and “Consolidated CDA creation performance” criteria do not require the C–CDA Release 2.1 Care Plan document template. Therefore, we have adopted this criterion to support the care planning use cases recited above and in the Proposed Rule.

Comments. A commenter recommended that we be more specific about which optional (e.g., “MAY”) items in the Health Concerns section of the C–CDA Care Plan document template should be required.

Response. As we stated in section III.A.2.b of this preamble regarding referenced standards for certification, if an element of a standard or IG is optional or permissive in any way, it will remain that way for testing and certification unless we specified otherwise in regulation. To the commenter's question, we have not specified otherwise in regulation. We note, however, that we would expect

⁷¹ <http://www.samhsa.gov/disorders>.

⁷² https://www.whitehouse.gov/sites/default/files/docs/pmi_privacy_and_trust_principles_july_2015.pdf; see also <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>.

⁷³ <http://www.hhs.gov/healthcare/facts/blog/2014/09/improving-health-care-delivery.html>.

⁷⁴ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379.

⁷⁵ <http://wiki.siframework.org/LCC+Pilots+WG>.

that health IT developers and providers would work together to determine whether the optional items are relevant and useful for the provider and patients intended to be served by the Health IT Module.

Comments. Most commenters expressed support for requiring a Health IT Module to be certified to the optionally designated sections in the C-CDA Release 2.0 Care Plan document template to meet this criterion. Commenters noted the Health Status Evaluations and Outcomes Section incorporates patient-reported outcomes to improve care and assist with the long-term goal of a truly integrated care plan. Commenters also suggested the Interventions Section (V2) would be useful for patients and family caregivers.

Response. We thank commenters for their feedback. We agree with commenters that the Health Status Evaluations and Outcomes Section and Interventions Section (V2) of the C-CDA provide important information for incorporating the patient's perspective in an effort to improve outcomes and the long-term goal of a longitudinal, dynamic, shared care plan. Accordingly, we have specifically identified these sections as required to be met for certification to this criterion.

Comments. A few commenters suggested that this criterion should also include a requirement for the receiving system of a C-CDA Care Plan to be able to reconcile the care plan information with the patient's record in the receiving system.

Response. While reconciliation is important and may be appropriate for any future iteration of this certification criterion, this functionality is outside the scope of our proposal. Therefore, we have not included in this criterion. We note that the industry continues to improve and develop advanced care planning standards and tools, which may address the incorporation of care planning information. As such, we will continue to monitor these developments for consideration in future rulemaking.

Comments. A few commenters suggested that we are conflating certain sections of the C-CDA Care Plan document template (e.g., Health Concerns and Goals) with items proposed in the Common Clinical Data Set.

Response. We refer readers to our response to this comment under the Common Clinical Data Set definition in section III.B.3 of this preamble.

• *Clinical Quality Measures—Record and Export*

2015 Edition Health IT Certification Criterion
§ 170.315(c)(1) (Clinical quality measures—record and export)

We proposed to adopt a 2015 Edition “clinical quality measures (CQM)—record and export” certification criterion that was revised in comparison to the 2014 Edition “CQM—capture and export” certification criterion (§ 170.314(c)(1)). In the Proposed Rule, we explained that we would align our use of the term “record” used in other 2014 and 2015 Edition certification criteria and proposed to call this certification criterion “CQM—record and export.” We proposed to require that a system user be able to export CQM data formatted to the Quality Reporting Document Architecture (QRDA) Category I standard at any time the user chooses for one or multiple patients and without subsequent developer assistance to operate. We also proposed to require that this certification criterion be part of the set of criteria necessary to satisfy the “2015 Edition Base EHR” definition (see also section III.B.1 of this preamble for a discussion of the 2015 Edition Base EHR definition). We solicited comment on the standard, including versions of QRDA Category I, we should adopt for this certification criterion with consideration given to where the industry may be with adoption of CQM and CDS standards over the next few years. In particular, we identified industry efforts to harmonize CQM and CDS standards. We asked for comment on the following version of QRDA or QRDA-like standards:

- HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012);
- HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) and the September 2014 Errata; or
- A QRDA-like standard based on the anticipated Quality Improvement and Clinical Knowledge (QUICK) Fast Healthcare Interoperability Resources (FHIR)-based DSTU.

In asking for comment, we sought to understand the tradeoffs stakeholders perceive in adopting each standard considering that the EHR Incentive Programs Stage 3 proposed rule proposed that health IT certified to the 2015 Edition would not be required until January 1, 2018, but that EPs, eligible hospitals, and CAHs participating in the EHR Incentive Programs Stage 3 objectives and measures could upgrade to health IT

certified to the 2015 Edition “CQM—record and export” certification criterion in 2017.

Comments. The majority of commenters recommended adopting the HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3, US Realm (“QRDA Category I Release 3 IG” or “Release 3”).⁷⁶ Commenters noted that CMS is using the QRDA Category I Release 3 IG for the 2015 update eCQM measures and the 2016 reporting period and recommended that we adopt this version for program alignment.⁷⁷ Commenters indicated Release 3 addresses known issues, fixes errors, and adds missing content compared to earlier versions of the QRDA Category I standard. Commenters also noted that Release 3 uses an incremental version of the underlying data model (the Quality Data Model 4.1.1) that is a step-wise approach toward harmonized CQM and CDS standards that stakeholders are developing.

While commenters were supportive of the work and direction on harmonized CQM and CDS standards to produce an anticipated QUICK FHIR-based DSTU, all commenters noted that no such standard is currently available and that it is premature to require any such standard for the 2015 Edition. Many commenters stated that stakeholders are still in the process of implementing QRDA and that we should adopt an incremental version of QRDA rather than pivot to the QUICK standard at this time.

Response. With consideration of commenters' feedback, we have adopted this criterion and the QRDA Category I Release 3 IG (both Volumes 1 and 2) for this criterion. In order to accommodate Release 3, we are amending the paragraph level at § 170.205(h) to move the standard that is required for the 2014 Edition “CQM—capture and export” criterion to § 170.205(h)(1), and adopting Release 3 at § 170.205(h)(2).

We agree with commenters that it is too early to adopt the QUICK CQM standards, but will continue to support the development and piloting of these harmonized CQM and CDS standards and reassess their appropriateness for certification at the time of a relevant future rulemaking.

Comments. Commenters expressed support for the proposal to permit users to export CQM data formatted to the

⁷⁶ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35.

⁷⁷ http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.

QRDA Category I standard for one or multiple patients at any time the user chooses and without subsequent developer assistance to operate. Some commenters requested clarification on what constitutes “without subsequent developer assistance to operate” and noted that batch export could be disruptive to overall EHR functionality. A few commenters asked for clarification of the use cases for export. Some commenters also requested clarification regarding who constitutes a “user,” with a few commenters suggesting that the “user” should only be those individuals with specific administrative privileges.

Response. We thank commenters for their support of the proposal. We have included in this criterion a requirement that a user be able to export a data file formatted in accordance with Release 3 for one or multiple patients that includes all of the data captured for each CQM to which the health IT was certified. We believe that the ability to export CQM data would serve two purposes. First, this functionality will allow a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis. Second, the export functionality gives providers the ability to export their results to multiple programs, such as those run by CMS, states, and private payers.

As we discussed in the 2015 Edition proposed rule (80 FR 16843), our intent is for users of certified health IT to be able to export CQM data formatted to the QRDA Category I standard for one or more patients without needing to request support from a developer. Stakeholders have noted that some health IT certified to the 2014 Edition “CQMs—capture and export” criterion do not provide users the ability to export QRDA Category I files “on demand” and that users must submit requests for the health IT developer to assist or perform the export function on their behalf. For testing and certification to the 2015 Edition “CQM—record and export” criterion, we would expect demonstration that the Health IT Module enables the user to export CQM data formatted to the QRDA Category I standard for one or more patients without needing additional developer support. We believe that providers and health systems should determine the protocols around when and how providers export CQM data, and we do not address this issue as part of certification as it is outside the scope of the ONC Health IT Certification Program.

We previously described a “user” in the 2014 Edition final rule (77 FR

54168) and continue to use the same description for the 2015 Edition. We expect the functionalities of this criterion to be available to any user, but the specification or limitation of types of users for this functionality is outside the scope of certification to this criterion. Providers have the discretion to determine the protocols for when and which users should use this functionality.

• *Clinical Quality Measures—Import and Calculate*

2015 Edition Health IT Certification Criterion
§ 170.315(c)(2) (Clinical quality measures—import and calculate)

We proposed to adopt a 2015 Edition “clinical quality measures (CQM)—import and calculate” certification criterion that was revised in comparison to the 2014 Edition “CQM—import and calculate” certification criterion (§ 170.314(c)(2)). We proposed to require that a system user be able to import CQM data formatted to the QRDA standard for one or multiple patients at any time the user chooses and without additional assistance to operate. We proposed to no longer include an exemption that would allow a Health IT Module presented for certification to § 170.315(c)(1), (c)(2), and (c)(3) to not demonstrate the data import capability. Rather, we proposed that a Health IT Module would be required to demonstrate that it could import data in order to be certified to this certification criterion even if it is also certified to provide “record and export” and “electronic submission/report” functions. We solicited comment on the version of QRDA or QRDA-like standards for individual patient-level CQM reports we should adopt for this certification criterion.

We stated that we intend testing to the 2015 Edition “CQM—import and calculate” certification criterion to include the import of a larger number of test records compared to testing for the 2014 Edition and to automatically de-duplicate records for accurate CQM calculation. We requested comment on this intent and the number of test records we should consider testing a Health IT Module for performing import and calculate functions.

Comments. The majority of commenters recommended adopting the HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3, US Realm (“QRDA Category I Release 3 IG” or “Release 3”). These commenters cited the same reasons for adopting Release 3

as recited under the 2015 Edition “CQM—record and export” criterion summarized above, and to which we refer readers. A few commenters recommended that QRDA Category III (aggregate level CQM reports) should not be required for this criterion.

Response. With consideration of commenters’ feedback, we have adopted this criterion and the QRDA Category I Release 3 IG (both Volumes 1 and 2) for this criterion. We note that we did not propose to require import of QRDA Category III files for this criterion and thus QRDA Category III is outside the scope of this criterion.

Comments. Commenters expressed support for the proposal to permit users to import CQM data formatted to the QRDA Category I standard for one or multiple patients at any time the user chooses and without subsequent developer assistance to operate. A few commenters asked for clarification of the use cases for import, and the justification for why all systems (even those previously considered “self-contained”) must demonstrate import. These commenters noted that some systems export CQM data to a third-party data aggregator or warehouse for calculation, whereas other EHR systems perform the calculation function itself. In the latter case, some commenters suggested it was not necessary for the system to be able to import CQM data. A few commenters were not supportive of requiring import using the QRDA Category I standard. Rather, they suggested import should be allowed using whatever standard or data structure is already being used by the system for import.

Response. We thank commenters for their support of the proposal and requests for additional clarifications. We have included in this criterion a requirement that a user be able to import a data file formatted in accordance with Release 3 for one or multiple patients that includes all of the data captured for each CQM to which the health IT was certified. We believe that the ability to import CQM data would serve two purposes. First, this functionality could streamline the testing and certification process by importing QRDA Category I files rather than systems needing to manually enter test patient data. Second, the import functionality can promote quality improvement and data sharing between systems by providing systems the ability to import CQM data from other systems in a standardized format. We note that ONC held a HITPC hearing on certification in 2014 and the HITPC recommended CQM certification as a top priority for providing value for

quality improvement and delivery system reform.⁷⁸ While we are not prescribing how data is imported into a system (e.g., mapped to a backend database or viewable to a provider as part of the patient record), we believe that requiring the import functionality can facilitate these use cases.

As we discussed in the 2015 Edition proposed rule (80 FR 16843), our intent is for users of certified health IT to be able to import CQM data formatted to the QRDA Category I standard for one or more patients without needing to request support from a developer. Stakeholders have noted that some health IT certified to the 2014 Edition “CQMs—import and calculate” criterion do not provide users to import QRDA Category I files “on demand” and that users must submit requests for the developer to assist or perform the import function on their behalf. For testing and certification to the 2015 Edition “CQM—import and calculate” criterion, we would expect demonstration that the Health IT Module enables the user to import CQM data formatted to the QRDA Category I standard for one or more patients without needing additional developer support. We believe that providers and health systems should determine the protocols around when and how providers import CQM data, and we do not address this issue as part of certification as it is outside the scope of the ONC Health IT Certification Program.

Comments. Commenters supported our intent to increase the number of test records used during the testing and certification process for this criterion. Most commenters recommended that rather than test to a certain number of records, testing should ensure that every pathway by which a patient can enter the numerator or denominator of the given measure is tested. Commenters were supportive of requiring health IT to demonstrate auto de-duplication of imported records during the testing process, but some commenters were concerned about how systems would be required to incorporate and reconcile imported data. Commenters requested clarification on whether duplicate records would be determined by a duplicate record ID number or by requiring the system to compare the data in two records and determine whether it is a duplicate. Commenters were concerned about the amount of work to reconcile data using the latter method.

⁷⁸ <http://www.healthit.gov/facas/calendar/2014/05/07/policy-certification-hearing>.

Response. We thank commenters for supporting use of an increased number of test records during the testing and certification process and we agree that testing should more robustly test the pathways by which a patient can enter the numerator or denominator of a measure, including exclusions and exceptions. In regard to auto de-duplication, while we have adopted the requirement, we have not prescribed how systems would demonstrate de-duplication or what systems must do with the imported data. We are providing flexibility in allowing health IT developers and providers to determine the most suitable methods for de-duplication and import of data for the given situation.

• *Clinical Quality Measures—Report*

2015 Edition Health IT Certification Criterion
§ 170.315(c)(3) (Clinical quality measures—report)

In the Proposed Rule, we stated that we intend to better align with the reporting requirements of other CMS programs, and thus, would propose certification policy for reporting of CQMs in or with annual PQRS and/or Hospital IQR program rulemaking anticipated in CY 2015. We explained that we anticipated proposing standards for reporting of CQMs that reflect CMS’ requirements for the “form and manner” of CQM reporting (e.g., CMS program-specific QRDA standards), allowing for annual updates of these requirements as necessary. Under this approach, we noted that the “CQMs—report” certification policy and associated standards for the 2015 Edition that support achieving EHR Incentive Programs requirements would be proposed jointly with the calendar year (CY) 2016 PFS and/or IPPS proposed rules. We clarified that we anticipated removing “electronic” from the name of this certification criterion because we expected that all functions proposed in the 2015 Edition health IT certification criteria to be performed or demonstrated electronically, unless specified otherwise. We also explained that we anticipated naming this certification criterion “report” instead of “submission” to better align with the language we use in other certification criteria that also require demonstration of a “reporting” functionality (i.e., to submit data).

We subsequently proposed a 2015 Edition “CQMs—report” certification criterion in the 2016 IPPS/LTCH PPS proposed rule that would require a Health IT Module to enable a user to electronically create a data file for

transmission of clinical quality measurement data using the “base” (i.e., industry-wide, non-program-specific) HL7 QRDA Category I and Category III standards, at a minimum (80 FR 24613–24614). We also proposed, as part of this proposed criterion, to permit optional certification for health IT in accordance with the CMS “form and manner” requirements defined in the CMS QRDA Implementation Guide.⁷⁹ CMS specified that health IT certified to this proposed certification criterion would be required to meet the proposed CEHRT definition for the EHR Incentive Programs.

As detailed in the FY 2016 IPPS/LTCH PPS proposed rule, we solicited comment on the appropriate versions of the Quality Reporting Document Architecture—Category I (individual patient level quality reports) and Category III (aggregate level quality reports) standards that should be adopted. In order to give full consideration to the comments received on the appropriate versions of the standards we should adopt, we did not adopt a “CQMs-report” certification criterion in the 2016 IPPS/LTCH PPS final rule (80 FR 49760). We stated that we anticipate adopting both the certification criterion and the appropriate versions of the standards in a subsequent final rule later this year. We also noted we intended to address comments received on both the proposed “CQMs-report” certification criterion and the versions of the standards in that same rule. We have used this final rule to address the comments and adopt the criterion and standards as specified below.

Comments. Commenters were supportive of the proposal to adopt a 2015 Edition certification criterion for CQM reporting. There was mixed feedback on whether a 2015 Edition “CQMs—report” criterion should require adherence to the HL7 QRDA Category I and Category III standards, or solely to the CMS QRDA Implementation Guide. The majority of commenters recommended that we not move to the Quality Improvement and Clinical Knowledge (QUICK) CQM⁸⁰ standards as they are unpublished and have not yet been balloted. Rather, commenters suggested we adopt incremental versions the QRDA standards because health IT developers and providers have focused efforts on fully supporting QRDA reporting. To this end, some commenters

⁷⁹ The CMS QRDA Implementation Guide can be accessed at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.

⁸⁰ <http://wiki.siframework.org/Clinical+Quality+Framework+Initiative>.

recommended that we adopt Release 3 of the QRDA Category I standard, and the November 2012 version of the QRDA Category III standard with the September 2014 Errata. Other commenters did not support Release 3 of the QRDA Category I standard, stating it was too immature for adoption. One commenter suggested that while Release 3 of QRDA Category I may be a new standard and require more work compared to Release 2 of QRDA Category I with the 2014 Errata, it offers more efficiencies and reduces errors that would ultimately improve eCQM processing.

Response. We thank commenters for their support for proposal and comments regarding the versions of standards. We believe that certification to the HL7 QRDA Category I and III standards provides a baseline for interoperability of CQM data as these standards are consensus-based and industry developed. Additionally, the HL7 QRDA standards are program-agnostic and can support a number of use cases for exchanging CQM data. Providers participating in CMS payment programs such as the EHR Incentive Programs, IPPS, or Hospital IQR may need to adhere to additional CMS QRDA reporting requirements as detailed in the CMS QRDA IG. However, we do not believe that all certified health IT is intended to be used for CMS reporting, and therefore have only included requirements for reporting to CMS (e.g., use of the CMS QRDA IG) as an optional provision within the criterion. We note that the CMS QRDA IG has been aligned with the HL7 QRDA Category I and III standards, but the CMS QRDA IG includes additional requirements beyond the HL7 IGs specific to CMS program reporting.

Our adoption of an optional provision to certify CQM reporting in the form and manner of CMS submission allows CMS to determine as part of its program requirements whether this optional provision of the CQM reporting criterion is required for participation in certain CMS programs. For example, CMS has proposed to revise the CEHRT definition to require health IT be certified to the provision of the “CQMs—report” criterion we have deemed optional (80 FR 41880–41881), which would affect, at a minimum, providers participating in the EHR Incentive Programs.

We agree with the comments supporting the adoption of Release 3 of the QRDA Category I IG as the IG will improve eCQM processing and reduce errors. The IG will also better align with the C-CDA Release 2.1 for purposes of interoperability as compared to QRDA Category I Release 2 with the 2014

Errata. Further, Release 3 of the QRDA Category I IG also aligns with the CMS 2015 update to eCQM measures for 2016 e-reporting (<https://ecqi.healthit.gov/ecqm>).

We agree with commenters that it is too early to adopt the QUICK CQM standards, but will continue to support the development and piloting of these harmonized CQM and CDS standards and reassess their appropriateness for certification at the time of a relevant future rulemaking.

In sum, after consideration of public comments, we have adopted a 2015 Edition “CQMs—report” criterion that requires a Health IT Module to enable a user to (electronically) create a data file for transmission of CQM data in accordance with:

- HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm) (both Volumes 1 and 2); and
- HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm) with September 2014 Errata.

All Health IT Modules must certify to the above standards to meet the criterion. As noted above, the criterion also includes an optional provision that requires the electronic creation of a data file for transmission of CQM data that can be electronically accepted by CMS (i.e., the form and manner of submission as specified in the CMS QRDA IG⁸¹).

In order to accommodate the new QRDA standards in the regulation text, we have revised the paragraph levels at § 170.205(h) and (k) to move the QRDA standards adopted in the 2014 Edition to § 170.205(h)(1) and (k)(1) respectively. We have also made a technical amendment to the regulation text for the 2014 Edition certification criteria for capturing, calculating, and reporting CQMs (at 45 CFR 170.314(c)(1), (c)(2), and (c)(3), respectively) to continue to reference the appropriate implementation specifications.

Comments. Commenters requested clarification on whether our proposal to adopt a 2015 Edition “CQMs—report” certification criterion through the 2016 IPPS/LTCH PPS proposed rule implies that annual recertification to the proposed criterion would be required as CMS updates the measure specifications and the CMS QRDA IG annually.

Response. We clarify that the proposal for a 2015 Edition “CQMs—report”

certification criterion would not require Health IT Modules to be recertified annually as part of the ONC Health IT Certification Program. However, in conjunction with our CMS colleagues, we also clarify that CMS requires that health IT be certified to the CMS QRDA IG and be updated to the latest annual measure specifications if providers intend to use the health IT to report CQMs electronically to CMS. This does not mean *recertification* is required each time the health IT system is updated to a more recent version of the CQMs. As CMS stated in the 2016 IPPS/LTCH PPS proposed rule, CMS intends to publish a request for information (RFI) on the establishment of an ongoing cycle for the introduction and certification of new measures, the testing of updated measures, and the testing and certification of submission capabilities (80 FR 24614–24615). We and CMS encourage readers to submit their comments and recommendations for consideration upon publication of the RFI.

- *Clinical Quality Measures—Filter*

2015 Edition Health IT Certification Criterion
 § 170.315(c)(4) (Clinical quality measures—filter)

We proposed to adopt a new 2015 Edition certification criterion that would require health IT to be able to record data (according to specified standards, where applicable) and filter CQM results at both patient and aggregate levels. We listed proposed data elements and vocabulary standards for some data elements to maintain consistency in the use of adopted national standards, and we clarified that a Health IT Module must be able to filter by any combination of the proposed data elements (i.e., by any one (e.g., provider type) or a combination of any of the data elements). We noted that the combination requirement is different than other certification criteria in the Proposed Rule in that it requires all combinations to be demonstrated for certification and not just one. We requested comment on the appropriateness of the proposed data elements for CQM filtering, including whether they are being captured in standardized vocabularies, and additional data elements that we should consider for inclusion and standardized vocabularies that might be leveraged for recording this information in health IT.

Comments. Many commenters were in support of adopting a new criterion for CQM filtering. Commenters noted the benefit for supporting the identification and reduction of disparities by filtering

⁸¹ Available at: https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm_library.html.

by patient demographics and problem list. A number of commenters also supported the list of proposed data elements as a good starting point with mature standards.

Response. We thank commenters for the feedback. Our overall goal for this functionality is to allow a provider to make a query for CQM results using one or a combination of data captured in the certified Health IT Module for quality improvement and quality reporting purposes. We agree with commenters on the value of this functionality for identification of health disparities, helping providers identify gaps in quality, and supporting a provider in delivering more effective care to subgroups of their patients. As such, we have adopted this certification criterion with the following modifications described below.

Comments. Some commenters noted it would be valuable to filter both QRDA Category I and Category III quality reports for this criterion to assist with individual patient quality improvement and for population health. One commenter noted that providing a filtered view to the provider would allow for easy spot-checking of health disparity trends to inform quality improvement projects.

Response. We thank commenters for the feedback and agree with the value of being able to filter QRDA I and Category III files as well as for providing a filtered view of the quality results for supporting the quality improvement and quality reporting use cases. QRDA Category I enables an individual patient-level quality report that contains quality data for one patient for one or more quality measures.⁸² The QRDA Category III standard enables an aggregate quality report containing calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time.⁸³ We have, therefore, required that a Health IT Module certified to this criterion must be able to filter CQM results at the patient and aggregate levels and be able to create a data file of the filtered data in accordance with the QRDA Category I and Category III standards, as well as be able to display the filtered data results in human readable format. To align with the versions of the QRDA standards we are adopting for the 2015 Edition “CQMs—record and export,” “CQMs—import and calculate,” and “CQMs—report” criteria, we have

adopted the following standards for this criterion:

- HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm) (both Volumes 1 and 2); and
- HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm) with September 2014 Errata.

Comments. One commenter expressed concern that the proposed criterion aims to achieve attribution of eCQM results to particular providers or groups of providers for participation in certain quality reporting programs, but that the proposed functionality to filter does not actually achieve attribution. The commenter noted that attribution requires a more complex approach than is currently proposed with the filtering of CQM results using different combinations of data, and suggested that it was appropriate for the industry to develop attribution standards in upcoming quality standards work.

Response. We thank the commenter for the feedback. We agree that proper attribution of eCQM results to a particular provider or group of providers will require a set of defined processes. We believe that the functionality in this criterion is a good step forward toward establishing such a process while the industry continues to improve eCQM standards as described further in the Proposed Rule (80 FR 16842–16843). We intend to continue working with stakeholders to establish standards and processes for proper attribution of quality measure results for consideration in future rulemaking.

Comments. A few commenters requested clarification of the language in the preamble and suggested that testing should not require that all possible combinations of data be demonstrated as it would be time-consuming and a very large number.

Response. We clarify that for testing Health IT Modules will not be tested to every possible combination of data, but that any combination could be tested at the discretion of the tester. We also note that we have not prescribed a workflow that must be demonstrated for certification in order to provide flexibility as long as the desired outcome can be achieved.

Comments. A few commenters indicated concern over the lack of alignment between the data and associated standards proposed for this criterion compared with our proposed 2015 Edition Common Clinical Data Set definition (80 FR 16871–16872), the data proposed in the 2015 Edition

“demographics” criterion (80 FR 16816–16817), and the request for comment for “future considerations for electronically specified measures using Core Clinical Data Elements” in the CMS 2016 Inpatient Prospective Payment System (IPPS) proposed rule (80 FR 24583–24584). Commenters suggested we work to ensure alignment of the data proposed in this criterion with those in the Common Clinical Data Set definition and proposed for the demographics criterion. Commenters also suggested we work with CMS on the Core Clinical Data Elements definition.

Response. We thank commenters for the recommendation to ensure data definitions are aligned. This criterion proposes a filter by “patient age” whereas the Common Clinical Data Set and demographics certification criterion specify “date of birth.” For this certification criterion, we intend that “patient age” is derived from the patient’s date of birth, but specify “patient age” because we believe that providers should be able to filter/query CQM results by the patient’s age rather than their date of birth. For example, the provider may query for patients older than a certain age, younger than a certain age, or between a range of ages. Therefore, we have adopted patient age as a data element for this certification criterion. We believe that all the other data in this criterion are aligned with the 2015 Edition Common Clinical Data Set and “demographics” criterion. We note that the “Core Clinical Data Elements” in CMS’ 2016 IPPS proposed rule is not being proposed for the 2016 program year and is a comment solicitation for future rulemaking. We intend to continue to work with CMS on alignment of data elements being required for capture across programs.

Comments. Commenters indicated some concern that providers may use multiple Tax Identification Numbers (TINs) and different levels of TIN/ National Provider Identifier (TIN/NPI) combinations. There was general support for the use of the NPI as a data element for this criterion.

Response. We believe that including TIN and NPI in this criterion offers a baseline for filtering by these data for certification. We would expect that any programs that may require CQM reporting using TIN and/or NPI would provide additional guidance on the level to use for participation in its programs. Therefore, we have adopted TIN and NPI as data elements for this criterion.

Comments. There was general support for use of the Healthcare Provider

⁸² Available at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35.

⁸³ Available at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286.

Taxonomy Code Set⁸⁴ for classifying provider types. Commenters indicated they were not aware of additional existing standards for provider types. A few commenters indicated concern that providers can select multiple codes in the NPI system that reflects their overall practice rather than their individual specialty, and that the code may have low reliability.

Response. We thank commenters for the feedback. We agree that the Healthcare Provider Taxonomy Code Set (the “Code Set”) is the best available standard for classifying provider type at this point in time, and have therefore adopted the CMS Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015 as the standard for provider type for this criterion (to the version updated April 2, 2015 as a minimum version for certification).⁸⁵ This crosswalk maps the Medicare Provider/Supplier type to the relevant healthcare provider taxonomy codes. It is our understanding that when a provider registers for an NPI number, they are required to select at least one provider type code from the Code Set, but may select more than one code. However, the provider is required to select one code as the primary code. It is also our understanding that the NPI record for a given provider contains all codes a provider selected, and so we would expect that CQM results could be filtered by any one of the provider’s selected codes (e.g., primary, secondary, tertiary, etc.). In order to ensure the NPI record is up-to-date, we would recommend that health care providers update and/or verify their registration annually in the CMS National Plan and Provider Enumeration System (NPPES)⁸⁶ to reflect the most accurate codes for the type of care the provider is currently providing. There are three methods by which an individual can access the NPI files: (1) Through a downloadable file, (2) through a display/query on the NPPES website, and (3) through an interface to the NPPES API. While health systems may keep their own internal records of NPI information for the providers practicing in their system, we recommend that any of the three above methods provides the most up-to-date information and would encourage systems to verify and use this information for their internal records.

⁸⁴ <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html>.

⁸⁵ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf>.

⁸⁶ <https://nppes.cms.hhs.gov/NPPES/Welcome.do>.

Comments. As discussed in the “transitions of care” criterion, a number of commenters suggested adoption of the U.S. Postal Service postal address standard for address as concerns patient matching. Commenters noted that the standard is widely supported by health care organizations today and is recommended by the American Health Information Management Association.⁸⁷ Some commenters were concerned about complexity in systems being able to choose the correct practice site that a patient was seen at as a patient may visit more than one practice site for a given provider. Another commenter suggested we consider the GS1 Global Location Number (GLN) standard⁸⁸ for practice site address as it is based on the USPS standard and could be filtered to provide a specific practice site address through the level of “party” and “location” using the GS1 GLN standard.

Response. We thank commenters for the input. At this point in time, we believe that use of the QRDA Category I and III standards which reference the HL7 postal format is an incremental step toward an industry standard. This is the same HL7 postal format standard referenced in C–CDA Release 2.1; and QRDA is based on the same underlying standard as C–CDA (i.e., the CDA). While we continue to analyze the USPS address standard⁸⁹ and other industry standards, we believe these standards were developed for other use cases (such as the shipping and delivery of mail or tracking medical products) than for querying for health information in the health care industry. We see a need for continued industry work to determine the appropriateness of existing standards and tools for normalizing postal address for health care uses cases, and intend to work with stakeholders in this space.

Testing and validation to the HL7 postal format in the QRDA standard is already available as part of Cypress testing⁹⁰ to QRDA for the 2014 Edition CQM certification criteria. We anticipate the Cypress testing tool for 2015 Edition CQMs criteria, including for CQM filtering, will carry over this testing and suggest that health IT developers and implementers adhere to the guidance in the QRDA Category I and III standards adopted for this criterion for the HL7 postal format. We believe it is best left to health IT developers and providers to

⁸⁷ <http://perspectives.ahima.org/wp-content/uploads/2014/12/PatientMatchingAppendixA.pdf>.

⁸⁸ <https://www.gs1.org/gln>.

⁸⁹ <http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf>.

⁹⁰ <http://projectcypress.org/>. Cypress is the testing tool used to test and certify products for CQMs in the ONC Health IT Certification Program.

work together to determine how to provide results for queries for patient seen at a particular practice site address at this point in time, and note that testing and certification will only test that a Health IT Module is able to filter CQM results by practice site address. Other programs that may require the use of this certification criterion may provide additional guidance on the definition of practice site address and guidance on attribution.

Comments. Commenters supported the Public Health Data Standards Consortium Source of Payment Typology Code Set⁹¹ for representing patient insurance. SDOs such as ANSI X12 and HL7 recognize the Source of Payment Typology Code Set for representing patient insurance in their standards.⁹²

Response. We have adopted the Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011) to represent patient insurance for this criterion.

Comments. Commenters expressed concern over the value set proposed to represent patient sex.

Response. We address the value set for patient sex in the “demographics” certification criterion discussed in section III.A.3 of this preamble, to which we refer readers. As noted above and recommended by commenters, we have adopted the same standard for this criterion as for the “demographics” certification criterion, which supports alignment and consistency.

Comments. Commenters expressed concern about the proposed requirement to filter all 900+ race and ethnicity codes in the “Race & Ethnicity—CDC” code system in PHIN VADS.

Response. We addressed the comments about the CDC Race and Ethnicity code set in the “demographics” certification criterion discussed elsewhere in this section of the preamble, to which we refer readers. We continue to believe in the value of querying by granular patient race and ethnicity for identification of health disparities and supporting a provider in delivering more effective care to sub-groups of their patients. As noted above and recommended by commenters, we have adopted the same standard for this criterion as for the “demographics” certification criterion, which supports alignment and consistency.

Comments. Commenters expressed concern on the level of complexity for

⁹¹ <http://www.phdsc.org/standards/pdfs/SourceofPaymentTypologyVersion5.0.pdf>.

⁹² <http://www.phdsc.org/standards/payer-typology.asp>.

filtering by SNOMED CT® codes for patient problem list.

Response. We acknowledge commenters' concerns about the level of complexity of filtering by SNOMED CT® codes for this certification criterion. To lessen the burden while continuing to provide value for quality improvement, we clarify that for testing and certification, a Health IT Module would only need to demonstrate it can filter by the parent level code in SNOMED CT® as the code system is designed in a hierarchical manner with more specific codes grouped under more general parent codes.

Comments. One commenter suggested we consider adding the CMS Certification Number (CCN) as an additional data element for this criterion as it is used by hospitals to report their CQM data to CMS.

Response. We thank the commenter for the suggestion. At this current point in time, we believe there are complexities with using the CCN as a filter for CQMs. For example, a certified Health IT Module may be certified partway through a reporting year. The CCN also represents a unique combination of certified Health IT Modules a provider is using to meet the CEHRT definition requirements. Thus, we are not clear on the use case that would be served in requiring a Health IT Module certified to this criterion to be able to filter CQM results by CCN. We will consider the use cases and implementation of using CCN for CQM filtering for the potential expansion of this criterion through future rulemaking.

- *Authentication, Access Control, and Authorization*

2015 Edition Health IT Certification Criterion

§ 170.315(d)(1) (Authentication, access control, and authorization)

We proposed to adopt a 2015 Edition “authentication, access control, and authorization” certification criterion that was unchanged in comparison to the 2014 Edition “authentication, access control, and authorization” criterion (§ 170.314(d)(1)).

Comments. Commenters were generally supportive of this criterion as proposed. One commenter suggested that we track the National Strategy for Trusted Identities in Cyberspace (NSTIC) initiative and the NSTIC Trustmark Framework pilot. One commenter was supportive of us adopting standards for multi-factor authentication for remote authentication to EHR systems, whereas another commenter pointed out that current approaches to multi-factor

authentication are costly and burdensome to implement. One commenter discussed digital signatures as they relate to the authenticity of medical documentation.

Response. We have adopted this certification criterion largely as proposed. We have made one minor revision by replacing the term “person” in the criterion with “user.” This revision is consistent with our use of the term “user” in the 2015 Edition. We note that, notwithstanding this revision, this criterion remains eligible for gap certification.

In response to comments on multi-factor authentication, we have not adopted multi-factor authentication as part of this criterion or in another criterion or requirement as we did not propose such functionality. We will, however, continue to track NSTIC. We will also monitor industry progress with multi-factor authentication and may consider multi-factor authentication certification for a future rulemaking as noted in our discussion of the HITSC recommendations below.

Digital signatures were proposed as part of the “electronic submission of medical documentation” criterion, but were not proposed as part of this criterion. Accordingly, we have not adopted such a requirement as part of this criterion. We may, however, consider digital signatures as part of a future rulemaking.

HITSC Recommendations

We received recommendations from the HITSC after the close of the public comment period for the Proposed Rule. The HITSC recommended the adoption of a certification criterion that would include capabilities to “continuously protect the integrity and confidentiality of information used to authenticate users.” The HITSC stated that the adoption of such a criterion would strengthen the authentication capabilities in currently certified health IT. The HITSC also recommended the adoption of a certification criterion for multi-factor authentication. These recommendations for the adoption of certification criteria must proceed through the processes outlined in sections 3001 and 3004 of the Public Health Service Act (HITECH Act), which may lead to a future rulemaking proposing the adoption of criteria that include capabilities recommended by the HITSC.

- *Auditable Events and Tamper-Resistance*

§ 170.315(d)(2) (Auditable events and tamper-resistance)

We proposed to adopt a 2015 Edition “auditable events and tamper-resistance” certification criterion that was unchanged in comparison to the 2014 Edition “auditable events and tamper-resistance” criterion (§ 170.314(d)(2)) and sought comment on two issues. First, given that it does not appear that the ASTM standard indicates recording an event when an individual’s user privileges are changed, we asked for comment on whether we need to explicitly modify/add to the overall auditing standard adopted in 170.210(e) to require such information to be audited or if this type of event is already audited at the point of authentication (*e.g.*, when a user switches to a role with increased privileges and authenticates themselves to the system). We also sought comments on any recommended standards to be used in order to record those additional data elements. We reiterated our policy in the 2014 Edition “auditable events and tamper resistance” certification criterion in that the ability to disable the audit log must be restricted to a limited set of users to meet this criterion, and we stated that we believe our certification criterion is appropriately framed within the parameters of what our regulation can reasonably impose as a condition of certification. With regard to feedback to the Voluntary Edition proposed rule that there may be some events recorded in the audit log that may be more critical to record than other events, we again sought comment on whether: There is any alternative approach that we could or should consider; there is a critical subset of those auditable events that we should require remain enabled at all times, and if so, additional information regarding which events should be considered critical and why; and any negative consequences may arise from keeping a subset of audit log functionality enabled at all times.

Comments. The majority of commenters requested that this criterion remain as proposed and be eligible for gap certification. Commenters overwhelmingly agreed that emergency access was being audited and is already covered under the ASTM E2147 standard. Some commenters expressed support for specifically auditing user privilege changes with the HITSC TSSWG recommending that this

2015 Edition Health IT Certification Criterion

criterion require events to be audited in accordance with NIST SP 800–92.⁹³

Most commenters, including the HITSC TSSWG, recommended that there should be no change in the requirements related to disabling and enabling the audit log. A commenter noted that determining when the audit log should or should not be enabled is best defined by end-users of Health IT Modules and not the health IT developers. Commenters representing consumer organizations suggested that the audit log should not be able to be disabled, which they argued would enhance consumer trust. Another commenter stated that any allowance for disabling the audit logs, for any reason, compromises the integrity of the auditing.

Commenters did not identify a critical subset of those auditable events that we should require remain enabled at all times. However, one commenter suggested that as an alternative to requiring the audit log to always be enabled, we should provide regulatory guidance on the specific information to be included in the audit log, such as is stipulated in the ASTM E2147 standard. The commenter also recommended that we provide clarity on the scope of the applicability of the ASTM standard as a part of that guidance when it comes to whether the intent is to include only natural person/end user accesses or other access such as “machine to machine.”

Response. We have adopted this criterion as proposed, except that we have revised the auditing standard referenced by this criterion and adopted in § 170.210(e)(1)(i)⁹⁴ to include a requirement to audit changes in user privileges. With consideration of public comments, we believe that this is an event that should be audited for the purposes of certification. We do not, however, believe that at this time certification should expand to an extensive list of auditable events as recommended by the HITSC TSSWG. Rather, we believe that certification should remain a baseline and health IT developers and providers can expand their auditing practices as appropriate.

We did not receive an overwhelming response or rationale from commenters that convinced us to change our approach to require that a Health IT Module not permit an audit log to be disabled. In fact, comments remained

mixed and the HITSC continued to support our current approach. As recited in the Proposed Rule, there are valid reasons for disabling the audit log. We continue to believe that it is appropriate to restrict the ability to disable the audit log to a limited set of users, which permits the end user to determine if, when, and by whom the audit log may be disabled. As to the alternative approach to always enabling the audit log, we note that we have chosen to maintain the current approach, but will consider as part of the finalizing of the 2015 Edition test procedure for this criterion what additional guidance we can provide related to auditable actions consistent with the ASTM E2147 standard.

- *Audit Report(s)*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(3) (Audit reports)

We proposed to adopt a 2015 Edition “audit reports(s)” certification criterion that was unchanged in comparison to the 2014 Edition “audit reports(s)” criterion (§ 170.314(d)(3)).

Comments. Commenters recommended that we adopt this criterion as proposed. A couple of commenters requested that we include additional functionality in this criterion, such as a filtering functionality (beyond sorting) and automated reporting without manual searches/sorting.

Response. We have adopted this criterion as proposed. We appreciate commenters’ suggested additional functionalities, but these functionalities are beyond the scope of our proposal. To note, certification serves as a baseline for health IT. We would expect health IT developers to incorporate such functionalities to possibly differentiate their products in the market or if specifically desired by their customers (e.g., providers).

- *Amendments*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(4) (Amendments)

We proposed to adopt a 2015 Edition “amendments” certification criterion that was unchanged in comparison to the 2014 Edition “amendments” criterion (§ 170.314(d)(4)). We noted that this certification criterion only partially addresses the amendment of protected health information (PHI) requirements of 45 CFR 164.526.

Comments. Commenters supported this criterion as proposed. A commenter requested clarification as to whether amendment steps such as request,

approval/denial, and updating are to be tracked as separate unique events or as a single event with a single timestamp. A couple of commenters suggested this criterion include the capability to maintain the provenance of amendments made by patients and other patient generated health data to reduce the numbers of errors.

Response. We have adopted this certification criterion as proposed. The “tracking” or auditing of events mentioned by the commenter is outside the scope of this criterion. Rather, we would expect such actions to be subject of an entity’s auditing technology and practices. We appreciate the suggestion to maintain provenance of amendments made by patients and other patient generated health data, but this is outside the scope of the functionality proposed for this criterion.

- *Automatic Access Time-Out*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(5) (Automatic access time-out)

We proposed to adopt a 2015 Edition “automatic access time-out” certification criterion that was unchanged in comparison to the 2014 Edition “automatic log-off” criterion (§ 170.314(d)(5)). In terms of the functionality within the criterion, we proposed to restate the language to require a Health IT Module to demonstrate that it can automatically stop user access to health information after a predetermined period of inactivity and require user authentication in order to resume or regain the access that was stopped. This proposal was based on feedback previously received from the HITSC Privacy and Security Workgroup (PSWG).⁹⁵ The PSWG noted in June 2014 that many systems are not session-based. Instead, systems may be stateless, clientless, and/or run on any device. The HITSC recommended that this certification criterion should not be overly prescriptive so as to inhibit system architecture flexibility. We agreed with the substance of the PSWG and HITSC recommendations and proposed to state the functionality required as specified above, noting that we do not believe this would have any impact on testing and certification as compared to testing and certification to the 2014 Edition “automatic log-off” criterion (i.e., the 2015 “automatic

⁹³ <http://csrc.nist.gov/publications/nistpubs/800-92/SP800-92.pdf>.

⁹⁴ We note that the ASTM E2147 standard has been reapproved (in 2013) with no changes. We have, therefore, revised the regulation text to reflect the reapproval. <http://www.astm.org/Standards/E2147.htm>.

⁹⁵ http://www.healthit.gov/facac/sites/faca/files/HITSC_PSWG_2015NPRM_Update_2014-06-17.pdf. The HITSC Privacy & Security Work Group changed names and became the HITSC Transport & Security Standards Work Group in July 2014.

access time-out” criterion would be eligible for gap certification).

Comments. Commenters expressed support for this criterion as proposed. The HITSC Transport and Security Standards Workgroup (TSSWG) again recommended that we change the language of the criterion to read “automatically terminate access to protected health information after a system- and/or administrator-defined period of inactivity, and reinitiate the session upon re-authentication of the user.”

Response. We thank commenters for their support. We continue to believe that the language offered by the TSSWG prescribes a particular session-based design and is not the most appropriate language for this criterion. As mentioned above, not all systems are session-based. Therefore, we have adopted this criterion as proposed.

- *Emergency Access*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(6) (Emergency access)

We proposed to adopt a 2015 Edition “emergency access” certification criterion that was unchanged in comparison to the 2014 Edition “emergency access” criterion (§ 170.314(d)(6)).

Comments. Commenters supported this criterion as proposed.

Response. We have adopted this criterion as proposed.

- *End-User Device Encryption*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(7) (End-user device encryption)

We proposed to adopt a 2015 Edition “end-user device encryption” certification criterion that was unchanged in comparison to the 2014 Edition “end-user device encryption” criterion (§ 170.314(d)(7)). We proposed to require certification to this criterion consistent with the most recent version of Annex A: Approved Security Functions (Draft, October 8, 2014) for Federal Information Processing Standards (FIPS) Publication 140–2.⁹⁶ We noted, however, that we do not believe that this would have any impact on testing and certification as compared to testing and certification to the 2014 Edition “end-user device encryption” criterion (*i.e.*, the 2015 “end-user device encryption” criterion would be eligible for gap certification).

⁹⁶ <http://csrc.nist.gov/publications/fips/fips140-2/fips1402annexa.pdf>.

Comments. Many commenters expressed support for leaving the certification criterion unchanged in comparison to the 2014 Edition “end-user device encryption” criterion. Many commenters also supported our proposal for using the most recent version of Annex A as cited in the Proposed Rule.

Response. We appreciate the support expressed by many commenters. We have adopted this certification criterion as proposed, including the updated version of Annex A.

Comments. Some commenters suggested that we expanded the functionality of this criterion to include server-side encryption or encryption of data in-motion. One commenter said that data should be encrypted when using cloud storage technologies. Another commenter requested clarification if this criterion applied to data at-rest or in-motion.

Response. As described in the 2014 Edition final rule (77 FR 54236–54238), the functionality included in the 2014 Edition certification criterion (and this 2015 Edition unchanged criterion) does not focus on server-side or data center hosted technology. We recognize that these implementations could employ a variety of different administrative, physical, and technical safeguards, including hardware-enabled security protections that would be significantly more secure than software oriented encryption capabilities. Rather, this criterion focuses on data locally stored on end-user devices after the use of the technology is stopped.

Comments. Some commenters stated that we should address encryption key management and key storage in this certification criterion.

Response. We agree with commenters that encryption controls depend on the encryption key remaining secure. However, this functionality is outside the scope of the proposed criterion. We also note that encryption key management often occurs outside of certified health IT and depends on the environment in which the certified health IT is deployed, and, as such, depends on organizational policy and security risk assessments. We encourage stakeholders to follow applicable guidance from the Office for Civil Rights (OCR)⁹⁷ and the National Institutes of Standards and Technology⁹⁸ for securing encryption keys.

- *Integrity*

⁹⁷ <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brguidance.html>.

⁹⁸ <http://csrc.nist.gov/publications/nistpubs/800-111/SP800-111.pdf>.

2015 Edition Health IT Certification Criterion
§ 170.315(d)(8) (Integrity)

We proposed to adopt a 2015 Edition “integrity” certification criterion that was unchanged in comparison to the 2014 Edition “integrity” criterion (§ 170.314(d)(8)). We did, however, propose a change in how a Health IT Module would be tested and certified to this criterion. We explained that the 2015 Edition “integrity” criterion would be tested and certified to support the context for which it was adopted—upon receipt of a summary record in order to ensure the integrity of the information exchanged (see § 170.315(d)(8)(ii)). Therefore, we stated that we expect that this certification criterion would most frequently be paired with the “ToC” certification criterion for testing and certification.

We sought comment on if, and when, we should set the baseline for certification to the 2015 Edition “integrity” certification criterion at SHA–2.⁹⁹ In support of this potential change, we noted that SHA–2 has much more security strength compared to the SHA–1 standard. We also pointed out that many companies, including Microsoft and Google, plan to deprecate SHA–1 no later than January 1, 2017.

Comments. Several commenters and the HITSC expressed support for increasing the integrity standard to SHA–2. One commenter pointed out that NIST has deprecated the use of SHA–1, whereas another commenter claimed that health IT would have to eventually get recertified to SHA–2 if we moved to SHA–2 at a later date (beyond the effective date of this final rule) or in a future edition. A few commenters requested that we wait until 2017 or 2018 to increase the standard to SHA–1.

Response. In 2012, NIST Special Publication 800–57¹⁰⁰ recommended that federal systems not be permitted to create new hashes using SHA–1 starting in 2014. Given that NIST, technology companies, and health IT developers are moving away from SHA–1, we believe now is the appropriate time to move towards the more secure SHA–2 standard. Therefore, we will make this new requirement effective with the effective date of this final rule. We note that there is no requirement obligating health IT developers to get their products certified to this requirement immediately, and we would expect

⁹⁹ <http://csrc.nist.gov/publications/fips/fips180-4/fips-180-4.pdf>.

¹⁰⁰ http://csrc.nist.gov/publications/nistpubs/800-57/sp800-57_part1_rev3_general.pdf.

health IT developers to not begin seeking certification to this criterion until later in 2016 for implementation in 2017 and 2018. We further note that certification only ensures that a Health IT Module can create hashes using SHA-2, it does not require the use of SHA-2. For example, users of certified health IT may find it appropriate to continue to use SHA-1 for backwards compatibility if their security risk analysis justifies the risk.

Consistent with this decision, we have also updated this criterion and standard to reference the most recent version of FIPS PUB 180-4, Secure Hash Standard, 180-4 (August 2015).¹⁰¹

2015 Edition Health IT Certification Criterion
§ 170.315(d)(9) (Trusted connection)

Please see the discussion under the “Application Access To Common Clinical Data Set” certification criteria later in this section of the preamble.

2015 Edition Health IT Certification Criterion
§ 170.315(d)(10) (Auditing actions on health information)

Please see the discussion under the “Application Access To Common Clinical Data Set” certification criteria later in this section of the preamble.

- *Accounting of Disclosures*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(10) (Accounting of disclosures)

We proposed to adopt a 2015 Edition “accounting of disclosures” certification criterion that was unchanged in comparison to the 2014 Edition “accounting of disclosures” criterion (§ 170.314(d)(9)). We noted that the 2015 Edition criterion is no longer designated “optional” because such a designation is no longer necessary given that we have discontinued the Complete EHR definition and Complete EHR certification beginning with the 2015 Edition certification criteria.

Comments. Commenters expressed support for this certification criterion as proposed. A commenter recommended removing the criterion until the HHS Office for Civil Rights (OCR) issues a final rule for its previously published proposed rule regarding accounting of disclosures (76 FR 31426).¹⁰² Other commenters recommended strengthening this criterion and

specifications to enhance the ability to identify inappropriate access inside an entity or organized health care arrangement and to provide reports with sufficiently relevant data.

Response. We have adopted this certification criterion as proposed. We initially adopted an “accounting of disclosures” certification criterion to supplement HITECH Act requirements and rulemaking by OCR (75 FR 2016-17 and 75 FR 44623-24) and believe there is value in its continue adoption as proposed. We appreciate the suggested revisions offered by commenters, but believe that alignment with an “account of disclosures” final rule will provide the most certainty and useful functionality for providers, while also mitigating any health IT development and implementation burdens that may accrue through compliance with potential multiple adopted versions of this certification criterion. We believe it is most appropriate to wait and consider the provisions of an “accounting of disclosures” final rule to be issued by OCR before making any revisions to this certification criterion. As currently adopted, health IT developers have the option of pursuing certification to this criterion if they deem it advantageous.

- *View, Download, and Transmit to 3rd Party*

2015 Edition Health IT Certification Criterion
§ 170.315(e)(1) (View, download, and transmit to 3rd party)

We proposed to adopt a 2015 Edition “view, download, and transmit to 3rd party” (VDT) criterion that was revised in comparison to the 2014 Edition “VDT” criterion (§ 170.314(e)(1)).

Clarified Introductory Text for 2015 Edition VDT Certification Criterion

We proposed to revise the introductory text to lead with “Patients (and their authorized representatives) must be able to use health IT to . . .” We also proposed to use this same phrase at the beginning of each specific capability for VDT to reinforce this point. We noted that this does not override or substitute for an individual’s right to access protected health information (PHI) in a designated record set under 45 CFR 164.524.

Comments. Many commenters voiced support for the inclusion of “authorized representative” in the introductory text of VDT, noting that specifically granting the patient’s authorized representative the ability to view/download/transmit patient health information reinforces the importance of the caregiver role on the care team and supports a vision of

patient-centered care. One commenter urged us to adopt the “personal representative” term used in HIPAA.

Response. We have adopted the proposed introductory language as it clarifies that these capabilities must enable patients and their authorized representatives. We decline to use the HIPAA term “personal representative.” Rather, we have adopted our proposal of “patients (and their authorized representatives)” to be consistent with the approach we have used in previous rulemakings that aligns with the use of the term under the EHR Incentive Programs. A “patient-authorized representative” is defined as any individual to whom the patient has granted access to their health information (see also 77 FR 13720). Examples would include family members, an advocate for the patient, or other individual identified by the patient. A patient would have to affirmatively grant access to these representatives with the exception of minors for whom existing local, state, or federal law grants their parents or guardians access without the need for the minor to consent and individuals who are unable to provide consent and where the state appoints a guardian (see also 77 FR 13720).

Additionally, consistent with our certification program approach to apply particular privacy and security certification criteria to a product’s certification based on the scope of capabilities presented, we have determined that this certification criterion would be clearer and more focused if we were to remove the secure access language included in (e)(1)(i) in favor of having a specific privacy and security certification criterion that would be applicable to this criterion. In transitioning this text, we have also made a conforming revision to note that the “technology” used would need to be “internet-based” which we believe is a more generally applicable and innovation supportive term compared to the user of the word “online,” which was part of the sentence that included the security specific language that we have removed.

Updated C-CDA and Common Clinical Data Set

We proposed to reference the updated version of the C-CDA (Draft Standard for Trial Use, Release 2.0) for the “VDT” criterion and noted that compliance with Release 2.0 cannot include the use of the “unstructured document” document-level template for certification to this criterion. We also solicited comment on whether we should limit the scope of the C-CDA

¹⁰¹ <http://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.180-4.pdf>.

¹⁰² <http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-13297.pdf>.

document created for the purposes of this criterion to just the CCD document template. We also solicited comment on whether we should require in this criterion to permit patients and their authorized representatives to select their health information for, as applicable, viewing, downloading, transmitting, or API based on a specific date or time, a period of time, or all the information available.

Comments. Multiple commenters supported the reference to C-CDA Release 2.0 document template. Some commenters voiced concern about adoption C-CDA Release 2.0 if backwards compatibility is not fully addressed. Other commenters suggested additional information that patients may need outside of the C-CDA, including referral summaries, discharge instructions, documents listed in the Patient Health Information Capture criterion, and nutrition and diet orders. Multiple commenters supported the focus on the creation of a CCD document template based on the C-CDA Release 2 for the “VDT” criterion, stating that it would be less confusing for consumers who may not be able to distinguish between different document types. In regard to our solicitation on time and date range functionality, multiple commenters were in support of adding such capabilities, while a few commenters did not agree with including this functionality.

Response. Consistent with our decision for the “ToC” criterion, we will reference C-CDA Release 2.1 in the “VDT” criterion. In response to public comment, we have narrowed the scope of the C-CDA document templates to only the CCD for this criterion. We emphasize that this requirement serves as a “floor” rather than a “ceiling” and that Health IT Modules and their purchasers may choose to add additional document types as appropriate for different practice and care settings.

We have included an updated Common Clinical Data Set for the 2015 Edition that includes references to new and updated vocabulary standards code sets. Please also see the Common Clinical Data Set definition in section III.B.3 of this preamble.

In consideration of public comments that focused on our comment solicitation around the addition of date and time filtering capabilities, we have decided to adopt such requirements as part of this criterion. We believe that adding this explicit functionality to the certification criterion provides specific clarity that patients should have certain baseline capabilities available to them when it comes to selecting the data (or

range of data) they wish to view, download, or transmit. Specifically, we have adopted within this criterion two timeframe filters that patients must be able to select and configure on their own. The first would ensure that a patient can select data associated with a specific date (to be viewed, downloaded, or transmitted) and the second would ensure that the patient could select data within an identified date range (to be viewed, downloaded, or transmitted), which must be able to accommodate the patient selecting a range that includes all data available to them. We also clarify that we are not including the ability to select a specific data element category as part of this requirement, but reiterate that these requirements represent a floor rather than a ceiling, and health IT developers may choose to add other functionalities as appropriate. The technology specifications should be designed and implemented in such a way as to provide maximum clarity to a patient (and their authorized representative) about what data exists in the system and how to interpret it, and we expect that health IT developers will make choices following design and usability best practices that will make it easier and clearer for patients to find and use their records.

Diagnostic Image Reports

We proposed to require that a Health IT Module would need to demonstrate that it can make diagnostic image reports available to the patient in order to be certified. We explained that a diagnostic image report contains a consulting specialist’s interpretation of image data, that it is intended to convey the interpretation to the referring (ordering) physician, and that it becomes part of the patient’s medical record.

Comments. Commenters were generally supportive of including diagnostic image reports and associated context in the “VDT” criterion. Some commenters requested clarification on where this data would be accessible within the C-CDA.

Response. We have adopted this proposal to include the diagnostic imaging report (including the consulting specialist’s interpretation) as a requirement in the “VDT” criterion. Health IT Modules may include this information in the “Results” section of the CCD. We clarify that unstructured data for the interpretation text is acceptable.

VDT—Application Access to Common Clinical Data Set

We have addressed all comments on this proposed provision under the “Application Access to Common Clinical Data Set” in this section of the preamble.

Activity History Log

We proposed to include “addressee” as a new data element in the 2015 Edition “VDT” criterion related to the activity history log. In the Proposed Rule, we noted that this transactional history is important for patients to be able to access, especially if a patient actively transmits his or her health information to a 3rd party or another health care provider.

Comments. Commenters were generally supportive of this new data element. One commenter suggested that we not include transmission status in the final rule because few patients actually transmit.

Response. We have adopted the new data element of “addressee” as part of the VDT criterion. While fewer patients may currently use “transmit” than “view” or “download,” we anticipate that more patients will use this functionality in the future and that this information will be helpful for transaction history.

Patient Access to Laboratory Test Reports

In the Proposed Rule, we noted recent regulatory changes addressing the intersection of the CLIA rules, state laws governing direct patient access to their laboratory test reports, and the HIPAA Privacy Rule. These regulatory changes converged in a final rule that permits a patient, or his or her “personal representative,” as applicable, to request a copy of the patient’s completed test reports directly from the laboratory or to request that the test results be transmitted to a designated person. To ensure fidelity of such reports regardless of the system delivering laboratory results to a patient, we proposed that a Health IT Module presented for certification to this criterion must demonstrate that it can provide laboratory test reports that include the information for a test report specified in 42 CFR 493.1291(c)(1) through (7); the information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and the information for corrected reports as specified in 42 CFR 493.1291(k)(2).

Comments. One commenter suggested that this requirement be removed until the C-CDA specification supports the requisite CLIA data referenced in the

Proposed Rule. Another commenter noted that some laboratory results require provider annotation and/or follow up testing before they can be released to the patient to avoid harm, particularly with certain sensitive tests such as HIV tests. Thus, a laboratory result awaiting provider annotation may not be fully “available” until the annotation is complete.

Response. We have adopted the proposed laboratory test reports requirement for the VDT criterion. We note that the C-CDA can support this information in a structured way using the “Result Observation Template” in the “Results” section. We recommend that health IT developers follow the best practices for use of these C-CDA templates as outlined by HL7 (see, e.g., HL7 Task Force Examples: http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force). Further, we strongly recommend an approach favoring coded data where possible and appropriate, and anticipate that future certification editions will require more extensively coded data.

Web Content Accessibility Guidelines (WCAG)

We proposed to modify the regulatory text hierarchy at § 170.204(a) to designate the WCAG 2.0 Level A (Level A) conformance at § 170.204(a)(1) instead of § 170.204(a). This would also require the 2014 Edition “VDT” certification criterion to be revised to correctly reference § 170.204(a)(1). We also sought comment on whether we should adopt WCAG 2.0 Level AA (Level AA) conformance requirements for the “view” capability included in the 2015 Edition VDT criterion, instead of the current Level A.

Comments. Many commenters representing the patient advocate community supported the increase to Level AA; additionally, the U.S. Access Board noted that other federal agencies and programs are moving toward Level AA. Other commenters said that Level A conformance was sufficient and that level AA is not needed and overly burdensome.

Response. We have adopted and retained the Level A requirement for this criterion. However, we have included Level AA as an optional component of this certification criterion via an “or” in the certification criterion so that if a developer so chooses it can demonstrate that a Health IT Module can meet Level AA. We reiterate that the “or” does not mean that a technology would need to meet both levels. At a minimum it would need to meet Level A. We note that such information would be listed with the product as part of its

Certified Health IT Product List (CHPL) listing. We believe this option adds transparency to what capabilities products include and can better inform purchasers. We have adopted Level AA as a standard at § 170.204(a)(2). Additionally, we have determined that the certification criterion’s requirements for the application of WCAG would be clearer if it were expressed in the general requirement at the paragraph 170.315(e)(1)(i) since WCAG needs to apply to all user viewable functionality and would equally apply to and include the user experience aspects of download and transmit.

“Transmit” Request for Comment

We requested comment on (1) whether we should include the Direct Project’s Implementation Guide for Direct Project Trust Bundle Distribution specification as part of certification for the “VDT” certification criterion; and (2) whether any additional requirements are needed to support scalable trust between Security/Trust Agents (STAs) as well as ways in which we, in collaboration with other industry stakeholders, could support or help coordinate a way to bridge any gaps.

Comments. One commenter noted that the proposed inclusion of the Direct Project’s Implementation Guide for Trust Bundle Distribution will be confusing because most of the Direct Project IG for the trust bundle focuses on creating a trust bundle, not consuming it. The commenter recommended pointing developers to Section 3.0 Trust Bundle Requestors for additional guidance, and that we support participation in existing trust communities such as the National Association for Trusted Exchange (NATE). Another commenter recommended that we require EHR and HISP vendors to preload all Blue Button Patient Trust Bundles into their systems so providers using these systems can transmit records using the Direct protocol.

Response. Our intent is to ensure that an individual who wants to transmit his or her health information to a third party has options to be able to do so, and those options should be easy and convenient. Individuals who are more concerned about sharing their data in transit can choose a more secure, simple option for transmitting this information. To provide greater flexibility for patients to effectively use the “transmit” capability and to ensure that patients have an easy and near universal ability to send their health information to a destination they select, we have adopted a more flexible approach for testing and certifying “transmit” as part of this

certification criterion. In order to satisfy this portion of the certification criterion a Health IT Module must demonstrate two forms of transmission:

- (1) Email transmission (of a CCD) to any email address;¹⁰³ and
- (2) An encrypted method of electronic transmission.

This approach will provide patients with a readily understood and convenient option to simply send their health information via email. Patients, under current HIPAA regulations,¹⁰⁴ may presently ask that data be disclosed to them via unencrypted email. Therefore, including email as an option for transmission capabilities is consistent with HIPAA as well as with common communications for other purposes. We also provide and encourage an encrypted option for transmitting their health information if they prefer or need to transmit their data with added security. There is a heightened interest in security of information in transit and at rest across all industries. As such, we encourage developers to provide innovative options for individuals to easily and efficiently protect their health information based on generally available mechanisms for security and new advances in this area. In either case—whether by email or an encrypted method—the goal is to support patients in transmitting their health information on demand to a third party of their own choice. We note that, for certification, the encrypted method would be subject to the 2015 Edition privacy and security certification framework, particularly the “trusted connection” certification criterion. We refer readers to section IV.C.1 (“Privacy and Security”) of this preamble for further discussion of the 2015 Edition P&S certification framework and to the “application access to Common Clinical Data Set” section of this preamble for more information of the “trusted connection” certification criterion.

In adding flexibility to this portion of the certification criterion, the other proposals and topics on which we sought comment are moot. However, we wish to reiterate that for the purposes of meeting the second form of transmission, the Direct protocol is an encouraged and viable method, especially since health IT developers have already been certified to this functionality for the purposes of 2014 Edition certification, and will also be

¹⁰³ Please see the OCR frequently asked questions for best practices regarding the use of email for transmitting health information: http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/570.html.

¹⁰⁴ 45 CFR 164.524 and related guidance.

certified to this functionality as part of 2015 Edition certification to support transitions of care requirements through the 2015 Edition “ToC” criterion. Additionally, we clarify that with respect to the second method, health IT developers have the flexibility to either establish an encrypted connection between two end points or, alternatively, secure the payload via encryption. In other words, we make no presumption and do not imply through the language in the second method that only one approach will satisfy testing and certification.

C–CDA Data Provenance Request for Comment

We refer readers to our response to this request for comment under the “ToC” criterion.

- *Secure Messaging*

2015 Edition Health IT Certification Criterion § 170.315(e)(2) (Secure messaging)

We proposed to adopt a 2015 Edition “secure messaging” certification criterion that was unchanged in comparison to the 2014 Edition “secure messaging” criterion (§ 170.314(e)(3)).

Comments. The majority of commenters supported this criterion as proposed. Some commenters suggested additional functionality for this criterion, including the ability to track responses to patient-generated messages, support languages other than English, and other forms of communication including audio, video, or images. A few commenters questioned whether patients’ devices would need to be secure and encrypted, and whether the encryption criteria would only apply to the message content. A commenter recommended that health IT developers should have to preload trust bundles. Another commenter suggested that health IT developers should be prohibited from charging significant add-on fees for secure messaging. Another commenter recommended that in-the-field surveillance is needed to ensure that health IT developers and providers were enabling this functionality. A commenter listed several issues associated with the EHR Incentive Programs Stage 3 objective and measure related to secure messaging, including the lack of a routine secure messaging use case for eligible hospitals and CAHs, that only certain types of secure messages would count, that the API alternative might drive down secure messaging using certified health IT, and that measurement should be based on those patients who “opt in.” This same

commenter also suggests that if the CMS proposal is adopted, the criterion should clearly define exclusion criteria.

Response. We have adopted this criterion with modification. We have removed the specific security requirements out of the criterion because the appropriate privacy and security (P&S) requirements will be applied through the 2015 Edition P&S certification framework finalized in this final rule. To clarify, a Health IT Module certified to this criterion will still need to demonstrate the same security requirements as included in the proposed criterion (patient/user authentication and encryption and integrity-protection), but there will be more flexibility in that a health IT developer can choose between message-level or transport level certification in accordance with § 170.315(d)(9). Certification to this criterion will also require certification to other privacy and security criteria under the P&S certification framework, including automatic log-off (§ 170.315(d)(5)) and the auditing criteria (§ 170.315(d)(2) and (3)). Our revisions to the criterion and approach are consistent with our overall approach to applying the appropriate privacy and security certification requirements to each 2015 Edition certification criterion. We refer readers to section IV.C.1 (“Privacy and Security”) of this preamble for further discussion of the 2015 Edition P&S certification framework, including specific application of the P&S certification framework to a Health IT Module presented for certification to the “secure messaging” criterion in conjunction with other certification criteria.

This criterion is no longer eligible for gap certification as the new hashing standard (a hashing algorithm with a security strength equal to or greater than SHA–2) applies to this criterion.

We appreciate the suggested additional functionalities for inclusion in this criterion (tracking responses, use of languages beyond English, and other forms of communication, and preloaded trust bundles), but the functionalities are beyond the scope of our proposal. We will consider these additional functionalities for a future edition of this criterion. We clarify in this final rule that the encryption requirements only apply to the message content and not to patients’ devices.

We cannot prescribe the fees health IT developers charge for their certified health IT, but note that our transparency provisions (§ 170.523(k)) require ONC–ACBs to ensure that health IT developers make public the types of costs they charge to enable certified

health IT. ONC–ACBs also conduct surveillance of certified health IT under the ONC Health IT Certification Program to ensure that health IT continues to function as initially certified. Surveillance can be initiated randomly or in response to complaints.

For concerns and questions related to the EHR Incentive Programs, we refer readers to CMS and the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**. We note that health IT certified to certification criteria that support percentage-based measures under the EHR Incentive Programs (i.e., this criterion) must also be able to record, at a minimum, the numerator for that measure per the CEHRT definition requirements and the “meaningful use measurement calculation” certification criteria (§ 170.315(g)(1) and (g)(2)).

- *Patient Health Information Capture*

2015 Edition Health IT Certification Criterion § 170.315(e)(3) (Patient health information capture)

In following the HITSC recommendation for Health IT Module functionality to store an advance directive and/or include more information about the advance directive, we proposed a 2015 Edition “patient health information capture” certification criterion that would “replace” the 2014 Edition “advance directives” certification criterion (§ 170.314(a)(17)) and apply to various patient health information documents. We stated that a Health IT Module would need to enable a user to: (1) Identify (e.g., label health information documents as advance directives and birth plans), record (capture and store) and access (ability to examine or review) patient health information documents; (2) reference and link to patient health information documents; and (3) record and access information directly and electronically shared by a patient.

We received general comments and comments on each of the capabilities included in the proposed criterion. We have divided and responded to the comments in a similar manner.

Comments. Commenters expressed general agreement with this criterion, with broad support across health IT developers, providers, consumers, and various advocacy groups. Commenters stated that this functionality could support addressing health disparities in populations that are less likely to execute healthcare planning documents

or provide health information to providers.

Response. We thank commenters for their feedback. We have adopted this criterion as proposed with the revisions and clarifications specified below. As adopted, we anticipate health IT developers will develop innovative and efficient ways to meet this criterion and simultaneously support providers accepting health information from patient.

Identify, Record, and Access Information Documents

Comments. Commenters universally supported this proposed provision.

Response. We thank commenters for their support. We have adopted the capabilities of this provision (identify, record, and access information documents) by combining them with the proposed provision of this criterion that included capabilities to record and access information directly and electronically shared by a patient. The capabilities to identify, record, and access patient health information documents are essentially a subset of the capabilities to record and access information directly and electronically shared by a patient, except for the proposed “identification” capability. Therefore, we have specifically retained the “identification” capability, while merging the other capabilities to finalize a provision that requires health IT to enable a user to identify, record, and access information directly and electronically shared by a patient (or authorized representative).

Reference and Link Documents

Comments. Most commenters supported this requirement, while some commenters did not agree that there was value in linking documents and others expressed security concerns. A commenter stated that a link could require additional log in credentials. A few commenters also expressed concerns regarding a system’s need to capture information from any external internet site, stating that a patient (intentionally or unintentionally) could provide a URL to the provider that contained a virus.

Response. The criterion focuses solely on the ability of the Health IT Module to be able reference (providing narrative information on where to locate a specific health information document) and link to patient health information. “Linking,” as described in the Proposed Rule, requires a Health IT Module to demonstrate it could link to an internet site storing a health information document. While an intranet link to a health information document might

suffice for provider use, a Health IT Module will still need to demonstrate the ability to link to an external site via the internet for the purposes of certification. The requirement of this provision does not go beyond this specified functionality.

This criterion is subject to the 2015 Edition privacy and security (P&S) certification framework adopted in this final rule. In this regard, a Health IT Module certified to this criterion would also need to be certified to the P&S certification criteria in § 170.315(d)(1) (authentication, access control, and authorization), (d)(2) (auditable events and tamper resistance), (d)(3) (audit reports), (d)(4) (amendments), (d)(5) (automatic log-off), and (d)(9) (trusted connection).¹⁰⁵ We believe these certification criteria and included capabilities will assist a provider in protecting its health IT system against potential security concerns. However, we note that certification is a baseline. Health IT developers and providers have the discretion to both determine what types of security features should be implemented (e.g., multi-factor authentication) with the functionality included in this criterion and whether to accept specific electronic information from a patient, such as a URL.

Record and Access Information Directly Shared by a Patient

Comments. Many commenters expressed support for this provision, including not specifying standards for compliance. A few commenters requested we identify standards or ensure compatibility with other standards such as the C-CDA or Direct messaging protocol. Most commenters sought clarification of this requirement. A couple of commenters suggested we drop this provision. A few commenters requested to know if this criterion was intended to directly support the proposed EHR Incentive Programs Stage 3 objective and measure regarding patient-generated health data and what types of patient health information was contemplated by this criterion. A commenter suggested making this functionality a separate criterion.

Response. The intent of this provision is to establish at least one means for accepting patient health information directly and electronically from patients in the most flexible manner possible. This approach means focusing on functionality and not standards. Further, we do not believe there are

¹⁰⁵ We refer readers to section IV.C.1 (“Privacy and Security”) of this preamble for further discussion of the 2015 Edition P&S certification framework.

appropriate standards that we could adopt that cover all the conceivable use cases.

This criterion was specifically included in the CEHRT definition to ensure, at a minimum, providers participating in the EHR Incentive Programs had this capability. While it could potentially be used to support the Stage 3 objective and measure regarding patient-generated health data, it was not proposed with the intention of it being the only means available for meeting the Stage 3 objective and measure. Rather, the goal was to set a foundation for accepting information directly from patients.

We do not seek to define the types of health information that could be accepted as we believe this should be as broad as possible. The types of health information could be documents as described in the Proposed Rule (e.g., advance directive or birth plans) or health information from devices or applications. The devices and applications could include home health or personal health monitoring devices, fitness and nutrition applications, or a variety of other devices and applications. In addition, patient health information could be accepted directly and electronically through a patient portal, an API, or even email.

We have determined that it is most appropriate to keep all the functionality in one criterion and combine capabilities as noted above. We emphasize that it is always possible to have multiple technologies certified together as a one “Health IT Module” to meet this criterion.

We note that we intend for “patient” to be interpreted broadly to include an authorized representative. For clarity, we have specified this intent in regulation.

• Transmission To Immunization Registries

2015 Edition Health IT Certification Criterion
§ 170.315(f)(1) (Transmission to immunization registries)

We proposed to adopt a 2015 Edition “transmission to immunization registries” certification criterion that was revised in comparison to the 2014 Edition “transmission to immunization registries” criterion (§ 170.314(f)(2)). To note, we have structured the comments we received and our responses based on the specific proposed provisions of this criterion.

Comments. Most commenters supported the proposed criterion. Many commenters noted the value of the proposed criterion to bi-directional data

exchange of immunization data, which was not supported by the functionality included in the 2014 Edition “transmission to immunization registries” criterion. Commenters also noted the importance of NDC and CVX codes, but expressed concern regarding issues with NDC codes as discussed in more detail below. One commenter suggested that intermediaries should be able to play a role, such as transformation of the data, in the transmission of immunization data and that only one system in the process of moving the immunization information from sender to public health agency should be required to be certified. Another commenter requested clarification if the criteria would be part of the Base EHR definition.

Response. We appreciate the support for the proposed certification criterion. We have adopted this certification criterion as proposed, but with an update to the proposed IG and the clarifications in response to comments discussed in detail below. We clarify for commenters that any health IT can be certified to this criterion if it can meet all the requirements of the criterion, which include context exchange and vocabulary standards but do *not* specify a transport standard or mechanism. We further clarify that this criterion is not included in the 2015 Edition Base EHR definition, but would support meeting one of measures under the public health objective of the EHR Incentive Programs Stage 3.

Implementation Guide for Transmission to Immunization Registries

We proposed to adopt the CDC’s updated implementation guide for immunization messaging, HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) (“Release 1.5”). We explained that the updated IG promotes greater interoperability between immunization registries and health IT systems, addresses issues from the previous release, and revises certain HL7 message elements to reduce data element recording differences between states and public health jurisdictions.

Comments. The majority of commenters supported adoption of Release 1.5, acknowledging that it resolves known issues in the previous release and offers improved support for standard data transmission. Some commenters noted that Release 1.5 includes references to the CDC Race and Ethnicity code set for purposes of the exchange of race and ethnicity data—which is more granular regarding race and ethnicity options for reporting when compared to the OMB standards.

These commenters asked for clarification of the required use of aggregated OMB standard values.

Response. We appreciate the support for Release 1.5. We note that the CDC has issued an addendum to Release 1.5.¹⁰⁶ The addendum consolidates the IG information that clarifies the conformance requirements, but does not specify additional substantive requirements. The addendum also provides value set requirements, general clarifications, and errata. The errata provides corrections to the length, data type, data type descriptions, usage, cardinality and/or value sets for various message elements, as well as corrections to, and addition of, conformance statements where they were mistakenly omitted. The addendum also includes clarifications to use of coding systems and value sets, additional examples of sending multiple forecast recommendations in a single message, usage of particular message elements (including those in the ORC and RXA segments), and updates to the value sets for patient eligibility status and vaccine funding source. We believe that Release 1.5 and the addendum are important components to advancing public health reporting and interoperability. We, therefore, have adopted HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 1, 2014) and HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5, Addendum (July 2015) for the transmission to immunization requirement. We clarify that to meet this criterion, health IT must comply with all mandatory requirements of Release 1.5 and its addendum, which would include the coding for race and ethnicity. The 2015 Edition “demographics” criterion and Common Clinical Data Set requirements related to race and ethnicity are not implicated by this criterion.

National Drug Codes for Administered Vaccinations

We proposed to require for certification that a Health IT Module be able to electronically create immunization information for electronic transmission to immunization registries using NDC codes for vaccines administered (*i.e.*, the National Drug Code Directory—Vaccine Codes, updates through January 15, 2015¹⁰⁷). For historical vaccines, we proposed to continue the use of CVX codes and

proposed to adopt the HL7 Standard Code Set CVX—Vaccines Administered, updates through February 2, 2015¹⁰⁸ as the baseline version for certification to the 2015 Edition.

We solicited comment on whether we should allow use of NDC codes for administered vaccines as an option for certification, but continue to require CVX codes for administered vaccines for the 2015 Edition. We also solicited comment on whether we should require CVX plus the HL7 Standard Code Set MVX—Manufacturers of Vaccines Code Set (October 30, 2014 version)¹⁰⁹ as an alternative to NDC codes for administered vaccines, and we sought feedback on the implementation burden for health IT developers and health care providers related to requiring CVX plus MVX codes versus NDC codes for administered vaccines.

Comments. The majority of commenters supported the use of NDC codes for administered vaccines and CVX codes for historical vaccines. Commenters stated that using NDC codes for administered vaccines is valuable because NDC codes provide more granular data than CVX codes, which can improve patient safety. Comments also stated that adopting NDC for administered vaccines aligns with on-going industry efforts related to vaccine data capture.

Some commenters suggested that mapping NDC codes to CVX could be burdensome for health IT developers and immunization registries, especially for a multiple component vaccine. Commenters noted that NDC codes are subject to change and codes are added and changed more frequently than CVX and MVX codes. Commenters further noted that the reuse of NDC codes by FDA can present difficulties regarding the transmission of immunization data using such codes. One commenter requested clarification on when NDC and CVX codes are required and noted the importance of clear requirements by states when NDC, CVX, or both codes would be needed.

Response. We appreciate commenters support for the use of NDC codes for administered vaccines and CVX codes for historical vaccines. For the purposes of administered vaccines, when an immunization is reported at the time it is administered and the actual product is known, the NDC code must be sent. We clarify that for when sending historical vaccines and the actual NDC code is not available, CVX codes can be

¹⁰⁶ <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html>.

¹⁰⁷ http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.

¹⁰⁸ <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>.

¹⁰⁹ <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx>.

sent as this method would be supported by health IT certified to this criterion. We understand the concerns regarding ensuring that the appropriate amount of information is available for immunizations and the concern regarding mapping between NDC and CVX for purposes of reporting. Therefore, we finalize a criterion that supports one set of codes to be used for administered vaccines at all times and another set of codes to be used for historical vaccines at other times. Therefore, we have adopted the August 17, 2015 version of the CVX code set as the minimum standards code set for historical vaccines. For purposes of administered vaccines, we have adopted the National Drug Codes (NDC)—Vaccine NDC Linker, updates through August 17, 2015 as the minimum standards code set. We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for further discussion of our adoption of minimum standards code sets and our decision to adopt these versions.

Immunization History and Forecast

We proposed that a Health IT Module would need to enable a user to request, access, and display a patient’s immunization history and forecast from an immunization registry in accordance with Release 1.5. We requested comment on whether we should include an immunization history information reconciliation capability in this criterion and the factors we should consider regarding the reconciliation of immunization history information. We explained that we believe that bidirectional exchange between health IT and immunization registries is important for patient safety and improved care. Immunization registries can provide information on a patient’s immunization history to complement the data in the health IT system. We noted that immunization registries also provide immunization forecasting recommendations according to the Advisory Committee on Immunization Practices (ACIP)’s recommendations. This information allows for the provider to access the most complete and up-to-date information on a patient’s immunization history to inform discussions about what vaccines a patient may need based on nationally recommended immunization recommendations.

Comments. Many commenters recognized the benefit of bi-directional data exchange to patient safety and population health, but some commenters expressed concern. Commenters primarily expressed concern that immunization registries

were not ready for bi-directional data exchange. Other commenters, however, noted that 28 Immunization Information Systems (IIS) (which, according to the commenter, represents about 52% of reporting systems) have notified the CDC of their query capabilities in production today using HL7 2.5.1. The commenter noted that the proportion would likely rise to near 100% by 2018. A few commenters questioned the utility of the ability to query a state registry.

Many commenters also expressed concern regarding reconciliation of forecasting data. One commenter noted that we should permit innovation to occur by not prescribing the workflows related to reconciliation. Another commenter noted that where bi-directional exchange is already in production, several different workflows exist within health IT products for reconciliation of immunization history.

Commenters expressed support for vaccine forecasting, but many commenters also stated that incorporating a forecast from an immunization registry into a health IT system could be difficult. Other commenters noted that some products already have forecasting functions, such as CDS functions for forecasting immunizations and, by association with forecasting, more complete data for allergies and contraindications.

Response. We have adopted the requirement for a Health IT Module to enable a user to request, access, and display a patient’s immunization history and forecast from an immunization registry in accordance with the Release 1.5 IG. We note that this criterion and its included capabilities are designed and focused on health IT, such as EHRs. In this regard, the goal is that health IT is certified to the criterion and its included capabilities (e.g., the Release 1.5 IG). Providers who adopt health IT certified to this criterion would then have the capabilities to meet requirements under the EHR Incentive Programs or query an IIS.

While we agree with commenters that some health IT (e.g., EHR products) may sometimes have a version of the immunization history or a version of the forecast that may differ from the immunization registry, we still believe that it is important for an EHR to receive the history and forecast from the registry. Based on compliance with the Release 1.5 IG, a user would be able to see and compare the forecast from the certified health IT (e.g., EHR products) with the forecast from the immunization registry. However, we note that this criterion does not prescribe a particular workflow or reconciliation

requirements. Providers and health IT developers may reconcile forecast and history information in a manner that best meets their needs for workflow and patient safety.

• Transmission to Public Health Agencies—Syndromic Surveillance

2015 Edition Health IT Certification Criterion

§ 170.315(f)(2) (Transmission to public health agencies—syndromic surveillance)

We proposed to adopt a 2015 Edition certification criterion for transmission of syndromic surveillance to public health agencies that was revised in comparison to the 2014 Edition version (§ 170.314(f)(3)) for the inpatient setting. We noted, however, that this proposed certification criterion is unchanged (for the purposes of gap certification) for the ambulatory setting. Given the varied adoption of methods for transmitting syndromic surveillance information to public health agencies from ambulatory settings, we proposed to continue to distinguish between ambulatory and emergency department, urgent care, and inpatient settings.

Comments. Commenters expressed support for distinguishing ambulatory settings from emergency department, urgent care and inpatient settings, especially given the variations in data requirements and readiness for data acceptance among the states. A commenter also noted that the distinction was appropriate because ambulatory systems are still evolving. Some commenters requested clarification of exclusions, active engagement, and other requirements to meet the syndromic surveillance measure under the EHR Incentive Programs.

Response. We appreciate the support offered by commenters and agree that it is appropriate to distinguish between settings. For questions related to the EHR Incentive Programs, we refer readers to CMS and the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

Emergency Department, Urgent Care, and Inpatient Settings

We proposed to adopt the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, September 2014 (“Release 2.0”), due to its improvements over previous versions.

Comments. The majority of commenters supported the proposed IG. One commenter suggested that, due to state variability, a standard should not

be referenced until at least 75% of states are committed to the use of a common standard. Other comments noted that Release 2.0 is the standard used by all states accepting hospital-based syndromic surveillance data. A commenter suggested that laboratory information be removed as required from the IG as states already collect this information under electronic laboratory reporting. One commenter suggested that there was a potential discrepancy between OMB value sets for race and ethnicity and the CDC Race and Ethnicity referenced code set in the IG. Another commenter asked for clarification of the “message frequency requirement of syndromic messages,” noting that the requirements within Release 2.0 may be burdensome for health IT developers. A commenter requested that certification include optional data elements within the IG.

Response. We appreciate the overall support for this criterion and the Release 2.0 IG. The CDC has recently published an updated version of the IG (April 21, 2015)¹¹⁰ that reflects work to correct errors and clarify ambiguities that were present in the proposed version (dating back to Release 1.0) as well as provide missing information. The CDC also recently published an addendum to the IG, titled “Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings” (“Erratum”).¹¹¹ The Erratum consolidates Release 2.0 information and clarifies existing conformance requirements of the IG. For example, it specifies conformance statements and conditional predicates that clarify message requirements. It also specifies value set requirements, provides general clarifications, and PHIN MG corrections. Overall, the April 21, 2015, updated version and the addendum do not create additional substantive requirements in comparison to Release 2.0. Rather, through the corrections, clarifications, and additional information the IG will improve testing, certification, implementation, and interoperability. Therefore, we have adopted this criterion with both the April 21, 2015, updated version and addendum.

We believe that the additional IG requirements for laboratory information are critical for public health as not all

laboratory information is reportable to public health through electronic laboratory reporting. These additional data elements enable public health jurisdictions to monitor the nation’s public health. We also clarify that the aggregated OMB value sets for race and ethnicity are acceptable within Release 2.0. We decline to make the optional elements of the IG required for certification as we believe that certification to the IG as published appropriately supports the use case. We also note that any IG instructions regarding the frequency of submission are outside the scope of certification as certification focuses on the technical capabilities of the Health IT Module presented for certification.

Ambulatory Syndromic Surveillance

We proposed to permit, for ambulatory setting certification, the use of any electronic means for sending syndromic surveillance data to public health agencies as well as optional certification to certain syndromic surveillance data elements. Due to the continued lack of mature IGs, we proposed to provide the option for health IT to electronically produce syndromic surveillance information that contains patient demographics, provider specialty, provider address, problem list, vital signs, laboratory results, procedures, medications, and insurance.

Comments. Most commenters stated that the majority of public health jurisdictions do not accept ambulatory syndromic surveillance data and that the standards for ambulatory syndromic surveillance are not mature. In particular, one commenter noted that syndromic surveillance standards for ambulatory encounters remain ill-defined and derivative of the inpatient standards. A few commenters stated that the “flexibility” in certification created burden on both providers and health IT developers to develop and implement health IT to meet the specified data elements without an established use case across public health jurisdictions.

Response. With consideration of public comments, comments received on a prior rulemaking (79 FR 54439–54441), and stakeholder feedback through public health outreach, we have determined to not adopt certification requirements for the ambulatory setting. Without mature standards and the widespread acceptance of ambulatory syndromic surveillance data across public health jurisdictions, sufficient reason does not exist to justify certification to the proposed functionality. To clarify, the PHIN 2.0 IG does support the *urgent care* ambulatory setting and would be

appropriate for use in that particular setting.

• *Transmission To Public Health Agencies—Reportable Laboratory Tests and Values/Results*

2015 Edition Health IT Certification Criterion

§ 170.315(f)(3) (Transmission to public health agencies—reportable laboratory tests and values/results)

We proposed to adopt a 2015 Edition certification criterion that was revised in comparison to the 2014 Edition “transmission of reportable laboratory tests and values/results” criterion (§ 170.314(f)(4)). We proposed to name this criterion “transmission to public health agencies—reportable laboratory tests and values/results” to clearly convey the capabilities included in this criterion as they relate to the intended recipient of the data. We proposed to include and adopt an updated IG, the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), DSTU R1.1, 2014 or “Release 2, DSTU R1.1” that addresses technical corrections and clarifications for interoperability with laboratory orders and other laboratory domain implementation guides. Given the improvements included in the updated IG (Release 2, DSTU R1.1), we proposed 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)(3). We also proposed the September 2014 Release of the U.S. Edition of SNOMED CT® and LOINC® version 2.50. We also proposed to make a technical amendment to the regulation text for the 2014 Edition criterion in order to have it continue to reference the appropriate standard and implementation specifications¹¹² after we restructured the regulatory text hierarchy at § 170.205(g) to accommodate our 2015 Edition proposal.

Comments. Most commenters supported the proposed criterion and standards. A few commenters expressed concern with the proposed IG related to use of OIDs, SPM–22 and SPM–24.

Response. We appreciate the expression of support for this criterion and the proposed standards. We note, however, that the HL7 Public Health and Emergency Response Workgroup is currently working on a newer version of

¹¹⁰ http://www.cdc.gov/nssp/documents/guides/syndrsurvmsgguide2_messagingguide_phn.pdf.

¹¹¹ <http://www.cdc.gov/nssp/documents/guides/erratum-to-the-cdc-phin-2.0-implementation-guide-august-2015.pdf>.

¹¹² 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.

the proposed IG that harmonizes with the HL7 Laboratory Results Interface (LRI) profiles. Harmonization with LRI will address the noted concerns as well as ensure alignment across laboratory IGs, including the LRI IG and the Laboratory Orders Interface (LOI) IG. This updated IG is not yet complete and cannot be adopted at this time. With these considerations, we do not believe it would be appropriate to adopt the proposed IG as health IT developer and provider efforts to meet and implement the requirements of the proposed IG would shortly be superseded by the updated IG. Therefore, we have not adopted the proposed IG. We have also not adopted the updated vocabulary standards because without a newer IG, there is little benefit from having health IT developers be tested and certified to updated vocabulary standards for this particular use case.

We have adopted a 2015 Edition “transmission to public health agencies—reportable laboratory tests and values/results” certification criterion that requires adherence to the same standards as we referenced in the 2014 Edition “transmission of reportable laboratory tests and values/results” criterion. Data from CDC and CMS indicates that over 80% of hospitals are already in the process of submitting electronic laboratory results using the previously adopted standards (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications, ELR 2.5.1 Clarification Document for EHR Technology Certification, and versions of SNOMED CT® and LOINC®). Our decision to adopt these same standards for the 2015 Edition criterion will ensure continuity in reporting and reduce burden for providers as well as health IT developers as this criterion is eligible for gap certification. We will continue to monitor the development of the updated IG and may consider proposing it for adoption through a future rulemaking to give health IT developers and providers another option to meet EHR Incentive Programs requirements for use of certified health IT to meet public health objectives and measures.

- *Transmission To Cancer Registries*

2015 Edition Health IT Certification Criterion
§ 170.315(f)(4) (Transmission to cancer registries)

We proposed to adopt a 2015 Edition “transmission to cancer registries” certification criterion that was revised in comparison to the 2014 Edition

“transmission to cancer registries” certification criterion (§ 170.314(f)(6)). We proposed to adopt the HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers Release 1 or “HL7 Release 1 IG”) to address technical corrections and clarifications for interoperability with EHRs and cancer registries, at § 170.205(i)(2). We proposed to include the September 2014 Release of the U.S. Edition of SNOMED CT® and LOINC® version 2.50 in this criterion. We proposed 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.

Comments. The majority of commenters expressed support for this criterion as proposed, including the HL7 Release 1 IG. Commenters stated that the proposed IG would provide substantial improvements in cancer reporting. Commenters also expressed support for incorporating updated versions of SNOMED CT® and LOINC® in this criterion as the vocabulary standards align with the IG requirements. Some commenters suggested mapping the IG to the currently used North American Association of Central Cancer Registries (NAACCR) format for any new cited standards. A commenter contended there was contradictory use of null values within the proposed IG. A few commenters expressed general concern regarding a lack of standardization across public health jurisdictions and registries to accept data according to proposed public health standards.

Response. We appreciate the overall support for this criterion and the HL7 Release 1 IG. The CDC recently published and updated version of the IG (HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, U.S. Realm)¹¹³ (“Release 1.1.”). Release 1.1 involves technical corrections to Release 1. No new content has been included. The templates in the IG were versioned due to the versioning of included templates (see the detailed section “Changes from Previous Version” in Volume 2 of this guide for a detailed view of these changes). The TNM Clinical Stage Observation was separated into a nested series of smaller, easier to implement templates. To note, the TNM Clinical Stage Observation

template had grown into a large, multi-level template that was difficult to implement and test. Similar changes were made to the TNM Pathologic Stage Observation template. Release 1.1 also addresses the contradictory use of nullFlavor attributes. A final notable revision is a constraint in the Cancer Diagnosis Observation that provided a choice between the TNM Pathologic Stage Observation and a No Known TNM Pathologic Stage Observation was replaced by a choice of standard constraints on the same two templates. This revision results in both an easier to understand specification and a simplified schematron file used for validation.

We have adopted this criterion with the updated IG, Release 1.1 (both Volumes 1 and 2). Commenters were supportive of our overall proposed approach and the proposed IG. As detailed above, Release 1.1 addresses errors, ambiguities, implementation issues, and commenters’ concerns. Therefore, the adoption of Release 1.1 will lead to improved implementation and interoperability.

Mapping to the NAACCR format is not included in the IG because the mapping rules are complex, and can change over time based on continued input and refinement by the cancer registry community. It is our understanding that the CDC will work closely with the cancer registry community to develop mapping rules for the IG and will incorporate the rules into the software tools CDC provides state cancer registries. In regard to concerns expressed about jurisdictional variations, all public health jurisdictions have all adopted the HL7 IG Release 1 for cancer reporting and will be moving to the updated version published by the CDC.

We have adopted a newer baseline versions of SNOMED CT® (September 2015 Release of the U.S. Edition) and LOINC® (version 2.52) for the purposes of certification. We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for further discussion of our adoption of minimum standards code sets and our decision to adopt these versions.

Cancer Case Information

We did not propose a “cancer case information” criterion as part of the 2015 Edition (80 FR 16854–855), but welcomed comments on this approach.

Comments. Commenters expressed agreement with discontinuing the “cancer case information” certification criterion, with a commenter noting the relevant data elements are already contained in the IG referenced in the

¹¹³ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=398.

2015 Edition “transmission to cancer registries” certification criterion. A commenter asked for clarification as to whether the discontinuation of this criterion affects the requirements of the “transmission to cancer registries” certification criterion and the requirements of the IG.

Response. We thank commenters for their feedback and have *not* adopted a “cancer case information” certification criterion. This decision has no impact on the requirements of the 2015 Edition “transmission to cancer registries” certification criterion or the requirements of the IG. Certification to the 2015 Edition “transmission to cancer registries” criterion requires a Health IT Module to demonstrate that it can create a file with the necessary cancer case information in accordance with the IG.

• *Transmission To Public Health Agencies—Electronic Case Reporting*

2015 Edition Health IT Certification Criterion

§ 170.315(f)(5) (Transmission to public health agencies—electronic case reporting)

We proposed to adopt a new 2015 Edition “transmission to public health agencies—case reporting” certification criterion, which would support the electronic transmission of case reporting information to public health agencies. We proposed to require a Health IT Module to be able to electronically create case reporting information for electronic transmission in accordance with the IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (September 5, 2014) standard. We noted that a Health IT Module would need to demonstrate that it can create and send a constrained transition of care document to a public health agency, accept a URL in return, be able to direct end users to the URL, and adhere to the security requirements for the transmission of this information.

In addition, we requested comment on whether we should consider adopting the HL7 FHIR Implementation Guide: SDC DSTU that would be balloted in mid-2015 in place of, or together with, the IHE Quality, Research, and Public Health Technical Framework Supplement.

Comments. Commenters expressed agreement on the importance of case reporting for public health. Some commenters expressed no concerns with the IHE profile, while others were unsure whether public health agencies had been sufficiently involved in the creation of the IG to warrant adoption in

the 2015 Edition. The latter commenters stated that the IG is primarily driven by clinical research requirements and has not been adopted by the public health community. Some commenters expressed concern with the potential use of the FHIR standard, stating it is immature and requires piloting and initial deployments before it can be adopted as a national standard. A commenter recommended that case reporting remain as a public health reporting option for the EHR Incentive Programs, but not be constrained by a requirement to use a specific standard.

Response. We understand commenters’ concerns with the current state of standards available and the continual evolution of standards. We also agree with commenters’ suggestions that an appropriate approach for this criterion would be to permit flexibility for case reporting by not referencing a specific content exchange standard for certification at this time.

We understand the industry is moving towards RESTful approaches and considering FHIR for different exchange patterns, including case reporting. To accommodate this evolution, we have not adopted the proposed IHE profile as part of this certification criterion or another exchange standard. We understand that there are certain functional requirements that a Health IT Module would need to support to enable electronic case reporting. Specifically, a Health IT Module would need to support the ability to electronically: (1) Consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to public health; (2) when a trigger is matched, create and send an initial case report to public health; (3) receive and display additional information, such as a “notice of reportability” and data fields to be completed; and (4) submit a completed form.

Public health agencies have, however, prioritized receiving the initial electronic case report form, while building the infrastructure to request supplemental data over time. Given the priority to receive the initial case report form, we have adopted the following functionality that supports the first two identified steps above. To meet this certification criterion, a Health IT Module must be able to (1) consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to public health to determine reportability; and (2) when a trigger is matched, create an initial case report that includes specific data (Common Clinical Data Set; encounter diagnoses;

provider name, office contact information, and reason for visit, and an identifier representing the row and version of the trigger table that triggered the case report).

The CCD template of the C-CDA Release 2.1 is currently the most viable approach for achieving step (2) above. We note, however, that the CDC and CSTE, with the HL7 Public Health and Emergency Response Working Group, are currently developing C-CDA and FHIR IGs to specify the data needed in the initial case report form and the data that would be provided in the information returned to the provider. As standards evolve, additional/supplemental data would likely be requested electronically about cases for which public health has received an initial case report that is deemed reportable. To support this additional data reporting, the future might include a FHIR-based approach that could utilize the FHIR Structured Data Capture (SDC) IG. Therefore, we believe this overall initial certification approach establishes necessary flexibility within the ONC Health IT Certification Program related to electronic case reporting in that as technical approaches evolve to accomplish electronic case reporting they can be certified. In the future, we may be able to consider a specific standard for certification through rulemaking.

We note that we have inserted “electronic” in the criterion name to emphasize the evolution of case reporting and the importance of *electronic* case reporting.

Comments. Many commenters expressed concern around the burden of connecting to multiple jurisdictions. One commenter noted a typical practice may be required to report in three different states using entirely different technologies, standards, and processes. The commenter recommended that the public health community develop a single reporting hub where all reports are submitted using the same technologies, standards, and processes. A couple of commenter suggested the use of a centralized platform or intermediary, which could streamline connectivity and reduce jurisdictional variability.

Response. We agree with commenters that a common public health interface or intermediary would reduce the burden on health IT developers and state and local public health agencies. The CDC and the public health community have made an investment in a centralized approach for receipt of electronic case reports. The CDC will identify a test harness and tool for all the functional requirements described

above. Additionally, as the CDC and public health approach matures to include other interfaces, the CDC will continue to monitor the development of standards to support these functional requirements. As noted above, this may lead to future rulemaking for the certification of electronic case reporting.

Comments. Many commenters identified a difference in the description of case reporting between the Proposed Rule and the EHR Incentive Programs Stage 3 proposed rule. In particular, a commenter compared the examples given for the Structured Data Capture standard proposed for case reporting in the Proposed Rule with the description of case reporting provided in the EHR Incentive Programs Stage 3 proposed rule, which focused on submitting information about reportable conditions to monitor disease outbreaks.

Response. The examples in the Proposed Rule of birth reports and other public health reporting were not examples of electronic case reporting. The examples were meant to illustrate how other public health domains have accomplished public health reporting through the use of the IHE RFD profile, upon which the IHE SDC profile proposed for adoption is based.

• *Transmission To Public Health Agencies—Antimicrobial Use And Resistance Reporting*

2015 Edition Health IT Certification Criterion

§ 170.315(f)(6) (Transmission to public health agencies—antimicrobial use and resistance reporting)

We proposed to adopt a new 2015 Edition certification criterion that would require a Health IT Module to be able to electronically create antimicrobial use and resistance reporting information for electronic transmission in accordance with specific sections of the HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (August 2013) (“HAI IG”). We explained that collection and analysis of data on antimicrobial use and antimicrobial resistance are important components of antimicrobial stewardship programs throughout the nation and electronic submission of antimicrobial use and antimicrobial resistance data to a public health registry can promote timely, accurate, and complete reporting, particularly if data is extracted from health IT systems and delivered using well established data exchange standards to a public health registry.

We proposed to test and certify a Health IT Module for conformance with the following sections of the IG in § 170.205(r)(1): HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69–72); Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54–56); and Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56–58). We explained that we would expect a Health IT Module presented for certification to this criterion to conform to all named constraints within the specified document template.

Comments. Most commenters expressed support for the adoption the proposed certification criterion and the included standard. A commenter stated that data on antimicrobial use and antimicrobial resistance are essential components of antimicrobial stewardship programs throughout the nation and is a highlight of the National Action Plan for Combating Antibiotic Resistant Bacteria. Another commenter stated that the data elements for antimicrobial use and resistance reporting are positive steps to help guide public health activities. Commenters also stated that the proposed criterion and standard would bolster the CDC’s National Healthcare Safety Network (NHSN) effort to develop coherent policies to fight antibiotic resistance through the reporting of standardized data about antibiotic use and resistance.

A commenter expressed concern about the pace and volume of changes between versions of the standard, the burden on health IT developers related to the timing of deployments, and that NHSN does not accept data submitted using prior versions. Another commenter expressed concern about state variations that are not addressed by this criterion, suggesting that the criterion and standard not be adopted until at least 75% of public health agencies are committed to adopting this standard.

A commenter stated that there were inconsistencies in the EHR Incentive Programs Stage 3 proposed rule related to this criterion regarding the standards available as well as a reference to meeting the measure four times. Another commenter suggested that the associated proposed measure under Stage 3 should be limited to eligible hospitals and CAHs (not EPs).

Response. We appreciate the overall support for this criterion and the IG. We

have adopted this criterion as proposed (with both Volumes 1 and 2 of the HAI IG). We intend to work with federal partners, such as the CDC, to eliminate or reduce any negative impacts on health IT developers resulting from the frequency of reporting changes or the manner in which changes are implemented in the associated program. We note that certification to the adopted version of the standard is what is necessary to meet the CEHRT definition under the EHR Incentive Programs. In regard to the concern about state variations, this data will only be collected by the CDC at the national level. The CDC is the only public health agency that needs to be able to receive these surveys electronically, which it is capable of doing. The use of a national interface for receipt avoids the problems associated with jurisdictional variation.

For concerns and questions related to the EHR Incentive Programs, we refer readers to CMS and the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

• *Transmission To Public Health Agencies—Health Care Surveys*

2015 Edition Health IT Certification Criterion

§ 170.315(f)(7) (Transmission to public health agencies—health care surveys)

We proposed to adopt a new 2015 Edition certification criterion for transmission of health care surveys to public health agencies that would require a Health IT Module to be able to create health care survey information for electronic transmission in accordance with the HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use (December 2014).¹¹⁴ We explained that the National Ambulatory Medical Care Survey (NAMCS) is a national survey designed to meet the need for objective, reliable information about the provision and use of ambulatory medical care services in the U.S. We also explained that the National Hospital Ambulatory Medical Care Survey (NHAMCS) is designed to collect data on the utilization and provision of ambulatory care services in hospital emergency and outpatient departments. We clarified that the proposed IG is intended for the transmission of survey data for both the NAMCS (e.g., for ambulatory medical care settings) and NHAMCS (e.g., for hospital ambulatory settings including

¹¹⁴ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=385.

emergency departments and outpatient departments). We noted that templates included in the IG align with the C-CDA standard. Additionally, we noted that the templates in the IG expand on the scope of the original NAMCS and NHAMCS survey data elements. The templates do not constrain the data collected to the narrow lists on the survey instruments; rather they allow any service, procedure or diagnosis that has been recorded.

Commenters. Commenters overwhelmingly supported the certification criterion and the use of the NHCS IG. Commenters expressed support for the continued effort to advance use of health care surveys as a means of improving patient outcomes. Commenters also expressed support for the specified data elements in the IG. One commenter, however, questioned the maturity of the standard and its adoption for certification at this time. Commenters requested clarification (and confirmation) on the surveys that must be supported for the purposes of certification. In particular, a commenter noted that it was not unclear whether the NAMCS and NHAMCS are the only surveys covered for certification.

A commenter requested information on the number of public health agencies that can electronically accept data in accordance with the IG.

Response. We appreciate the overall support for this criterion and the IG. We have adopted this criterion as proposed. While we understand the concerns that this standard may not be fully mature, the IG has gone through the HL7 balloting process and is currently a Draft Standard for Trial Use, which is no different than other standards in use today and adopted as part of the 2015 Edition. Further, the CDC has been working with providers to submit this data electronically using these surveys prior to this rulemaking. As such, we believe that the IG is mature enough for widespread adoption.

We clarify that, as proposed, certification would cover the entire NHCS IG. The NHCS IG consists of the National Hospital Care Survey, NHAMCS, and NAMCS. In the Proposed Rule, we focused on clarifying that the NHAMCS and NAMCS were included in the IG and the changes in the surveys as compared to past versions. However, all three surveys are covered by the NHCS IG and will be covered as part of testing and certification.

All public health agencies may not be able to receive this data electronically and that variability across jurisdictions could be problematic. However, this data will only be collected by the CDC at the national level. The CDC is the

only public health agency that needs to be able to receive these surveys electronically, which it is capable of doing. The use of a national interface for receipt avoids the problems associated with jurisdictional variation.

- *Automated Numerator Recording*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(1) (Automated numerator recording)

We proposed to adopt a 2015 Edition “automated numerator recording” certification criterion that was unchanged in comparison to the 2014 Edition “automated numerator recording” criterion. We noted that the test procedure for this criterion would be different from the 2014 Edition “automated numerator recording” certification criterion in order to remain consistent with the applicable objectives and measures required under the EHR Incentive Programs.

Comments. We received mixed comments in response to the proposal. A number of commenters supported this criterion as proposed. A few commenters stated that this criterion has been burdensome and complicated as its implementation has led to interruptions in provider workflows solely for the purposes of reporting on measures under the EHR Incentive Programs. These commenters further contended that such data collection was unrelated to improving patient care. A commenter suggested that we ensure that the terminology used in the test procedures aligns with that used for the measures under the EHR Incentive Programs. Another commenter suggested that this criterion should be gap certification eligible if the associated EHR Incentive Programs measure has not changed from Stage 2.

Response. We have adopted this criterion as proposed. This criterion is included in the CEHRT definition under the EHR Incentive Programs. This certification criterion could ease the burden of reporting particularly for small providers and hospitals (77 FR 54184). We will work to ensure consistency with the test procedure and the measures under the EHR Incentive Programs. As stated in the 2015 Edition proposed rule (FR 80 16868), this certification criterion’s gap certification eligibility is “fact-specific” and depends on any modifications made to the specific certification criteria to which this criterion applies. As mentioned above and in the Proposed Rule, it would also depend on changes to the test procedure that are made to align

with applicable objectives and measures under the EHR Incentive Programs.

We have changed the term “meaningful use” to “EHR Incentive Programs” and removed “objective with a” in the first sentence of the criterion to more clearly align with the terminology and framework used under the EHR Incentive Programs.

- *Automated Measure Calculation*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(2) (Automated measure calculation)

We proposed to adopt a 2015 Edition “automated measure calculation” certification criterion that was unchanged in comparison to the 2014 Edition “automated measure calculation” criterion. We proposed to apply the guidance provided for the 2014 Edition “automated measure calculation” certification criterion in the 2014 Edition final rule that a Health IT Module must be able to support all CMS-acceptable approaches for measuring a numerator and denominator in order for the Health IT Module to meet the proposed 2015 Edition “automated measure calculation” certification criterion.¹¹⁵ We also proposed that the interpretation of the 2014 Edition “automated measure calculation” certification criterion in FAQ 32¹¹⁶ would apply to the 2015 Edition “automated measure calculation” certification criterion. We also noted that the test procedure for this criterion would be different from the 2014 Edition “automated measure calculation” certification criterion in order to remain consistent with the applicable objectives and measures required under the EHR Incentive Programs.

Comments. We received mixed comments in response to our proposal. One commenter noted that this criterion and included functionality has value for helping providers understand their quality outcomes and performance on certain EHR Incentive Programs measures. A few commenters stated that this criterion has been burdensome and complicated as its implementation has led to interruptions in provider workflows solely for the purposes of reporting on measures under the EHR Incentive Programs. These commenters further contended that such data collection was unrelated to improving patient care.

¹¹⁵ 77 FR 54244–54245.

¹¹⁶ <http://www.healthit.gov/policy-researchers-implementers/32-question-11-12-032>.

Commenters were generally supportive of applying the guidance provided in the 2014 Edition final rule (77 FR 54244–54245) and the guidance in FAQ 32 to the 2015 Edition criterion. One commenter suggested that this criterion should be gap certification eligible if the associated EHR Incentive Programs measure has not changed from Stage 2. This commenter recommended that ONC provide revised draft test procedures for this criterion for public comment prior to the release of the final rule.

Response. We have adopted this criterion as proposed. This criterion is included in the CEHRT definition under the EHR Incentive Programs. This certification criterion could improve the accuracy of measure calculations to reduce reporting burdens for EPs, eligible hospitals, and CAHs (77 FR 54244). We will apply the guidance in the 2014 Edition final rule and FAQ 32 to this criterion.

As stated in the 2015 Edition proposed rule (FR 80 16868), this certification criterion's gap certification eligibility is "fact-specific" and depends on any modifications made to the specific certification criteria to which this criterion applies. As mentioned above and in the Proposed Rule, it would also depend on changes to the test procedure that are made to align with applicable objectives and measures under the EHR Incentive Programs. We note that draft test procedures for the 2015 Edition were released with the publication of the Proposed Rule¹¹⁷ and were open for public comment from March 20, 2015, to June 30, 2015. Revised draft final test procedures will be made available after publication of this final rule for public review and comment.

We have changed the first use of the term "meaningful use" to "EHR Incentive Programs" and removed its second use in the criterion. We have also removed the phrase "objective with a." We have made these revisions to more clearly align with the terminology and framework used under the EHR Incentive Programs.

- *Safety-Enhanced Design*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(3) (Safety-enhanced design)

We proposed to adopt a 2015 Edition "safety-enhanced design" (SED) certification criterion that was revised in comparison to the 2014 Edition "safety-enhanced design" criterion. We

proposed to include seventeen (17) certification criteria (seven new) in the 2015 Edition SED certification criterion (80 FR 16857), and for each of the referenced certification criteria and their corresponding capabilities presented for certification, we proposed to require that user-centered design (UCD) processes must have been applied in order to satisfy this certification criterion. We stated we intend to continue submission of summative usability test results to promote transparency and foster health IT developer competition, spur innovation, and enhance patient safety. With this in mind, we sought comment on whether there are other certification criteria that we omitted from the proposed SED criterion that commenters believe should be included.

Comments. Comments generally supported the proposed SED criterion, but questioned the number of certification criteria included. Some commenters questioned rationale for adding the new criteria and the carryover inclusion of the "drug-drug, drug-allergy interaction checks for CPOE" criterion, while other commenters generally questioned whether this criterion has contributed to improving usability or patient safety. A few commenters suggested that this criterion only apply to criteria that involve tasks performed by clinical users. A couple of commenters expressed concern about the additional burden the new criteria presented.

Response. We thank commenters for their feedback. We have adopted the proposed SED with revisions and clarifications. We note that 5 criteria proposed for inclusion in the SED criterion have not been adopted as part of the 2015 Edition. These criteria are: "vital signs," "eMAR," "incorporate laboratory tests/results," and both "decision support" criteria. Consequently, these criteria cannot be included in the SED criterion and, therefore, there is only a net increase of two criteria subject to the SED criterion. We do not believe this will create a significant burden for health IT developers and note that many developers have had their products certified to the 2014 Edition versions of the criteria included in the 2015 SED criterion and the 2014 Edition SED criterion. The criteria included in the 2015 Edition SED criterion are as follows (emphasis added for the new criteria):

- Section 170.315(a)(1) Computerized provider order entry—medications
- Section 170.315(a)(2) Computerized provider order entry—laboratory

- Section 170.315(a)(3) Computerized provider order entry—diagnostic imaging
- Section 170.315(a)(4) Drug-drug, drug-allergy interaction checks
- Section 170.315(a)(5) *Demographics*
- Section 170.315(a)(6) *Problem list*
- Section 170.315(a)(7) Medication list
- Section 170.315(a)(8) Medication allergy list
- Section 170.315(a)(9) Clinical decision support
- Section 170.315(a)(14) *Implantable device list*
- Section 170.315(b)(2) Clinical information reconciliation and incorporation
- Section 170.315(b)(3) Electronic prescribing

We believe the inclusion of criteria such as "demographics," "implantable device list," "drug-drug, drug-allergy interaction checks for CPOE," and "CDS" are appropriate because data entry errors and poor user interfaces for responding to alerts and interventions can compromise patient safety. While we do not have empirical data related to the "effectiveness" of the SED criterion, we believe that our approach contributes to improving usability and patient safety through both the application of the SED criterion's requirements to a significant number of health technologies being used in the market today and in the future as well as through the SED information being available on the CHPL for stakeholder review and evaluation.

NISTIR 7742 Submission Requirements, New Requirements and Compliance Guidance

We proposed to include the specific information from the NISTIR 7742 "Customized Common Industry Format Template for Electronic Health Record Usability Testing" (NIST 7742)¹¹⁸ in the regulation text of the 2015 Edition SED criterion to provide more clarity and specificity on the information requested in order to demonstrate compliance with this certification criterion. We reiterated that the information must be submitted for each and every one of the criteria specified in the 2015 Edition SED criterion to become part of the test results publicly available on the Certified Health IT Product List (CHPL). We specified that all of the data elements and sections must be completed, including "major findings" and "areas for improvement."

We identified the table on page 11 of NISTIR 7742 for the submission of demographic characteristics of the test

¹¹⁷ <http://healthit.gov/policy-researchers-implementers/2015-edition-draft-test-procedures>.

¹¹⁸ http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907312.

participants because it is important that the test participant characteristics reflect the audience of current and future users. In accordance with NISTIR 7804 (page 8),¹¹⁹ we recommended that the test scenarios be based upon an analysis of critical use risks for patient safety, which can be mitigated or eliminated by improvements to the user interface design.

We strongly advised health IT developers to select an industry standard process because compliance with this certification criterion requires submission of the name, description, and citation (URL and/or publication citation) of the process that was selected, and we provided examples of method(s) that could be employed for UCD, including ISO 9241–11, ISO 13407, ISO 16982, ISO/IEC 62366, ISO 9241–210 and NISTIR 7741. We explained that, in the event that a health IT developer selects a UCD process that was not an industry standard (i.e., not developed by a voluntary consensus standards organization), but is based on one or more industry standard processes, the developer may name the process(es) and provide an outline of the process in addition to a short description as well as an explanation of the reason(s) why use of any of the existing UCD standards was impractical. We also noted that health IT developers can perform many iterations of the usability testing, but the submission that is ultimately provided for summative usability testing and certification must be an expression of a final iteration, and the test scenarios used would need to be submitted as part of the test results. We noted that we do not expect developers to include trade secrets or proprietary information in the test results.

Comments. Commenters expressed appreciation for the clarity the proposed 2015 Edition SED criterion provided in terms of requirements. Some commenters agreed with including major findings and areas for improvement sections in the summative testing documentation, while other commenters did not support the public reporting of major findings and areas for improvement because they argued that the information is usually meant to inform the developer.

Many commenters expressed concern on the proposed limitation for measuring user satisfaction. Commenters mentioned that user satisfaction ratings are often now based on non-standard surveying processes. Commenters suggested that we not solely rely on task-based satisfaction

measures and consider post-session satisfaction measures. Commenters suggested that we use industry standard, literature-recognized satisfaction measures such as the Single Ease-of-use Question, System Usability Scale, or Software Usability Measurement Inventory.

Response. We thank commenters for their feedback. We have finalized our proposed requirements with one revision. In response to comments, we now also permit the submission of an alternative acceptable user satisfaction measure to meet the requirements of this criterion. Stated another way, a health IT developer could meet the proposed NIST 7742 based approach for user satisfaction or provide documentation of an alternative acceptable user satisfaction measure. We will take into consideration the other user satisfaction measures identified by commenters in the development and finalization of the 2015 SED test procedures and related guidance for complying with this criterion and particularly the user satisfaction measure.

Number of Test Participants

We recommended following NISTIR 7804¹²⁰ “Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records” for human factors validation testing of the final product to be certified, and recommended a minimum of 15 representative test participants for each category of anticipated clinical end users who conduct critical tasks where the user interface design could impact patient safety (e.g., physicians, nurse practitioners, physician assistants, nurses, etc.) and who are not include employees of the developer company. We additionally requested comment on whether we should establish a minimum number(s) and user cohort(s) for test participants for the purposes of testing and certification to the 2015 Edition under the ONC Health IT Certification Program.

Comments. We received a large number of comments in response to this request for comment with the majority of commenters advocating for a required minimum number of test participants and some commenters advocating for established user cohorts per capability. Commenters strongly stated that establishing a minimum number of participants would allow for proper validation of testing results. Many commenters advocated for a minimum of 12 or 15 participants. Another large

contingent of commenters advocated for 10 participants. A few commenters suggested that the number of test participants should remain as guidance. A few commenters also stated that a high participant threshold could be burdensome to small developers.

Commenters generally recommended that cohorts should be consistent with the capability under testing. Some commenters stated, for example, that clinicians would not be appropriate for a more administrative capability such as recording demographics. Commenters gave mixed responses on whether this described approach should be required or simply guidance.

Response. As a general matter, the more users tested, the more likely developers will be able to identify and remedy design flaws. To this point, research suggests that “with ten participants, 80 percent of the problems are found whereas 95 percent of the problems are found with twenty participants.”¹²¹ For the purposes of this final rule, we have adopted a provision as part of this criterion that requires 10 participants per criterion/capability as a mandatory minimum for the purposes of testing and certification. We believe this minimum is responsive to commenters and will ensure more reliable summative testing results. We also believe this number will balance any potential burden for health IT developers, including small developers. However, we strongly encourage health IT developers to exceed the mandatory minimum in an effort to identify and resolve more problems.

We agree with commenters that cohorts should not be limited to clinicians but instead consist of test participants with the occupation and experience that aligns with the capability under testing. We believe, however, that it would be too restrictive and complicated to establish cohort requirements per criterion. Instead, we continue to recommend that health IT developers follow NISTIR 7804 for human factors validation testing of the final product to be certified. We will also work with NIST to provide further guidance as needed.

Request for Comment on Summative and Formative Testing

We requested comment regarding options that we might consider in addition to—or as alternatives to—summative testing. We asked whether a standardized report of formative testing

¹¹⁹ http://www.nist.gov/customcf/get_pdf.cfm?pub_id=909701.

¹²⁰ http://www.nist.gov/customcf/get_pdf.cfm?pub_id=909701.

¹²¹ Pg. 42. NISTIR 7804 Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records http://www.nist.gov/healthcare/usability/upload/EUP_WERB_Version_2_23_12-Final-2.pdf

could be submitted for one or more of the 17 proposed certification criteria for which summative testing would be required, if formative testing reflected a thorough process that has tested and improved the usability of a product. Additionally, we asked for feedback on the requirements for such a formative testing report and on how purchasers would evaluate these reports.

Comments. Commenters acknowledged the benefits of formative testing, with some noting that it can act as a risk management process before getting to summative testing. The majority of the commenters, however, were against formative testing as an alternative to summative testing. One commenter stated that one of the main objectives for the SED criterion is to allow purchasers and consumers to compare competing products on the quality of human interaction and usability. The commenter contended that test results are therefore publicly available for this purpose on the Certified Health IT Product List (CHPL). The commenter maintained that this essential function cannot be fulfilled, however, with the results of formative testing as they cannot be compared across products but only between the iterations of a single product. The commenter noted, as other commenters did, that formative tests are intended to identify problems rather than produce measures. A few commenters suggested that we require both summative and formative testing, while a few other commenters suggested formative testing was not reliable or useful.

Response. We thank commenters for their insightful feedback. We agree with the commenters that see value in formative testing, but we also agree with the commenters that contend it should not be a substitute for summative testing for the purposes of this criterion. With this in mind and consideration of the potential burden imposed by requiring both summative and formative testing, we have decided to retain summative testing requirements and not adopt formative testing requirements.

Retesting and Certification

We stated that we believe that ONC-ACB determinations related to the ongoing applicability of the SED certification criterion to certified health IT for the purposes of inherited certified status (§ 170.550(h)), adaptations and other updates would be based on the extent of changes to user-interface aspects of one or more capabilities to which UCD had previously been applied. We specified that ONC-ACBs should be notified when applicable changes to user-interface aspects occur,

and we included these types of changes in our proposal to address adaptations and updates under the ONC-ACB Principles of Proper Conduct (§ 170.523).

We discuss the comments received on this proposal and our response under section IV.D.6 of this preamble.

- *Quality Management System*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(4) (Quality management system)

We proposed to adopt a 2015 Edition “quality management system” certification criterion that was revised in comparison to the 2014 Edition and proposed that all Health IT Modules certified to the 2015 Edition would need to be certified to the 2015 Edition QMS criterion “quality management system” criterion. We proposed to require the identification of the Quality Management System (QMS) used in the development, testing, implementation, and maintenance of capabilities certified under the ONC Health IT Certification Program. We specified that the identified QMS must be compliant with a quality management system established by the federal government or a standards developing organization; or mapped to one or more quality management systems established by the federal government or standards developing organization(s). We stated that we will not permit health IT to be certified that has not been subject to a QMS and that we will require health IT developers to either use a recognized QMS or illustrate how the QMS they used maps to one or more QMS established by the federal government or a standards developing organization(s) (SDOs). We explained that we encourage health IT developers to choose an established QMS, however, developers may also use either a modified version of an established QMS, or an entirely “home grown” QMS. In cases where a health IT developer does not use a QMS established by the federal government or an SDO, we proposed to require the health IT developers illustrate how their QMS maps to one or more QMS established by the federal government or SDO through documentation and explanation that links the components of their QMS to an established QMS and identifies any gaps in their QMS as compared to an established QMS. We added that documentation of the current status of QMS in a health IT development organization would be sufficient. We also provided a list of QMS standards established by the

federal government and SDOs (80 FR 16858).

Comments. The majority of commenters supported the proposed criterion and its approach, with broad support across health IT developers, providers, and consumers. A commenter questioned whether we provided the appropriate example standards, citing ISO 14971 as a risk-management standard for medical devices and not a QMS standard. Other commenters stated that the identified standards were too focused on medical devices. A few commenters indicated that other standards and processes should be considered as acceptable means for meeting this criterion. These commenters specifically mentioned ISO 12207, IEEE 730, IEEE 1012, ISO 14764, ISO 80001, the health IT QMS standards under development through the Association for the Advancement of Medical Instrumentation (AAMI), and the accreditation process software quality systems run by the Capability Maturity Model Integration Institute (CMMI). A few commenters expressed concern that it would be burdensome to map an internal QMS to one or more QMS established by the federal government or SDO, including more burdensome on small health IT developers.

A few commenters requested clarifications. A commenter noted that health IT developers use agile software development practices and requested clarification if these processes would be sufficient for certification. A commenter asked how this criterion would apply to a self-developer or open source software. A couple of commenters asked how Health IT Modules would be evaluated against this criterion, including what type of documentation would be required for mapping and whether a documented combined QMS approach for the entire Health IT Module would be sufficient in lieu of a capability by capability identification.

Response. We thank commenters for their feedback and support. We have adopted this criterion as proposed with further clarification in response to comments. We note that this criterion applies to any health IT presented for certification to the 2015 Edition, including self-developed and open source software that is part of the Health IT Module because one of the goals of this criterion is to improve patient safety through QMS.

We expect that ONC-ACBs will certify health IT to this criterion in the same manner as they certify health IT to the 2014 Edition QMS criterion, but accounting for any differences that are finalized through the 2015 Edition ACD

test procedure. To this point, we have removed the term “compliant” from the provision requiring identification of a QMS compliant with a quality management system established by the federal government or a standards developing organization. Similar to the mapping provision, the focus and intent of the provision (and the criterion as a whole) is the identification of the QMS, not a determination of compliance by the ONC-ACB. We note that the identification of a single QMS is permitted for a Health IT Module, which is consistent with testing and certification to the 2014 Edition QMS certification criterion.

As noted in the 2014 Edition final rule (77 FR 54191), we agree that existing standards may not explicitly state support for agile development methodologies and that such methods may be part of an optimal QMS. As such, documented agile development methodologies may be used in meeting the mapping provision of this criterion. We will issue further compliance guidance as necessary, including through the 2015 Edition QMS test procedure. This guidance will include updated identification of QMS standards and more specification of documentation requirements necessary to meet this criterion. Overall, we do not believe this criterion presents a significant burden as many health IT products have been previously certified to the 2014 Edition QMS criterion and most, if not all, developers (with previously certified products or not) should have QMS documentation readily available for their health IT products as a standard practice.

- *Accessibility-Centered Design*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(5) (Accessibility-centered design)

We proposed to adopt a new 2015 Edition “accessibility-centered design” certification criterion that would apply to all Health IT Modules certified to the 2015 Edition and require the identification of user-centered design standard(s) or laws for accessibility that were applied, or complied with, in the development of specific capabilities included in a Health IT Module or, alternatively, the lack of such application or compliance.

We proposed to require that for each capability that a Health IT Module includes and for which that capability’s certification is sought, the use of a health IT accessibility-centered design standard or compliance with a health IT accessibility law in the development,

testing, implementation, and maintenance of that capability must be identified. Further, we proposed to permit that a health IT developer could document that no health IT accessibility-centered design standard or law was applied to the health IT’s applicable capabilities as an acceptable means of satisfying this proposed certification criterion. We added that the method(s) used to meet this proposed criterion would be reported through the open data CHPL. We solicited comment on whether the standards and laws identified in the Proposed Rule were appropriate examples and whether we should limit the certification criteria to which this criterion would apply.

We explained that the proposed certification criterion would serve to increase transparency around the application of user-centered design standards for accessibility to health IT and the compliance of health IT with accessibility laws. We stated that this transparency would benefit health care providers, consumers, governments, and other stakeholders, and would encourage health IT developers to pursue the application of more accessibility standards and laws in product development that could lead to improved usability for health care providers with disabilities and health care outcomes for patients with disabilities.

We also proposed to revise § 170.550 to require ONC-ACBs follow this proposed approach and referred readers to section IV.C.2 of the Proposed Rule’s preamble for this proposal.

Comments. The vast majority of commenters supported the proposed criterion and its approach, with broad support across health IT developers, providers, and consumers. One commenter suggested that we narrow the list of example standards to those that have the widest applicability to EHRs. Another commenter suggested that the focus should be on more accessibility-centered standards such as ISO 9241–20 (2008) “Ergonomics of Human-System Interaction—Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services,” ISO 9241–171 (2008) “Ergonomics of Human-System Interaction—Part 171: Guidance on software accessibility,” Section 508 of the Rehabilitation Act, and Section 504 of the Rehabilitation Act. A few commenters suggested that this criterion would have a significant development burden for health IT developers. One commenter requested clarification on how testing and certification will be conducted.

Response. We thank commenters for their feedback. We have adopted this criterion as proposed. We will work with our federal partners (e.g., NIST, Administration for Community Living and Aging Policy, and the HHS Office for Civil Rights) and consider comments on the final test procedure for this criterion in providing more precise identification and guidance on accessibility-centered standards and laws. We believe this criterion poses minimal burden on health IT developers as it only requires health IT developers to *identify* relevant standards or laws; *and*, alternatively, permits a health IT developer to state that its health IT product presented for certification does not meet any accessibility-centered design standards or any accessibility laws. That said, as noted above, we remind health IT developers and providers that the existence of an option to certify that health IT products do not meet any accessibility design standards or comply with any accessibility laws does not exempt them from their independent obligations under applicable federal civil rights laws, including Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act that require covered entities to provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

We expect that ONC-ACBs will certify health IT to this criterion in the same manner as they certify health IT to the 2014 Edition QMS criterion, but accounting for any differences that are finalized through the 2015 Edition ACD test procedure. We will issue further compliance guidance as necessary.

- *Consolidated CDA Creation Performance*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(6) (Consolidated CDA creation performance)

We proposed to adopt a new certification criterion at § 170.315(g)(6) that would rigorously assess a product’s C-CDA creation performance (for both C-CDA Release 1.1 and 2.0) when it is presented for a Health IT Module certification that includes within its scope any of the proposed certification criteria that require C-CDA creation (e.g., “transitions of care” at § 170.315(b)(1)). We explained that to implement this proposal, we would amend § 170.550 to add a requirement that ONC-ACBs shall *not* issue a Health IT Module certification to a product that

includes C-CDA creation capabilities within its scope, unless the product was also tested and satisfied the certification criteria requirements proposed at § 170.315(g)(6). If the scope of certification included multiple certification criteria that require C-CDA creation, we noted that § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each. Specifically, we proposed that three technical outcomes be met: reference C-CDA match, document template conformance, and vocabulary conformance.

We noted that we coordinated with our colleagues at NIST and understand that NVLAP-Accredited Testing Laboratories would retain the C-CDA files created under test and contribute them to an ONC-maintained repository.

Comments. A number of commenters expressed support for the proposal for this certification criterion that would test a Health IT Module's C-CDA creation performance as proposed. Some commenters suggested that the gold standard needs to be specific on what to do with optionality permitted in the C-CDA standard. A few commenters requested clarifications on how the gold standard would be structured, whether it would be one or multiple documents, and whether the testing would be done through an automated tool or by visual inspection.

Response. We thank commenters for their support and have adopted a C-CDA creation performance certification criterion with the following changes described below. As discussed in the 2014 Edition Release 2 proposed rule (79 FR 10899), we continue to believe in the value of this capability to promote the ability of providers to exchange C-CDA documents and subsequently be able to parse and use the C-CDA received. This is especially important for interoperability when the C-CDA standard allows for optionality and variations.

We intend to publish sample gold standard C-CDA documents on www.healthit.gov or another ONC-maintained repository for the public to review and provide comment. We also anticipate that there will be multiple gold standard documents for each C-CDA document template we require for this criterion with variations in each to test optionality for which the C-CDA standard allows. With respect to testing, we anticipate that testing will be performed, at a minimum, through a conformance testing tool and could also include visual inspection as necessary to verify reference C-CDA match,

document template conformance, and vocabulary conformance.

Comments. Similar to comments received to other certification criteria such as "transitions of care," commenters did not support the proposal to be able to create C-CDA documents in accordance with both C-CDA Releases 1.1 and 2.0.

Response. We have adopted C-CDA Release 2.1 for this certification criterion for the same reasons as noted in the preamble for the "transitions of care" criterion.

C-CDA Document Templates

We proposed that Health IT Modules would have to demonstrate compliance with the C-CDA creation performance functions of this criterion for the following C-CDA Release 2.0 document templates:

- Continuity of Care;
- Consultation Note;
- History and Physical;
- Progress Note;
- Care Plan;
- Transfer Summary;
- Referral Note; and
- Discharge Summary (for inpatient settings only).

Comments. A few commenters suggested that ONC not require certification to all proposed document templates and indicated that not all document templates are applicable to every setting. They also cited potential development burdens with the proposed scope.

Response. As discussed in the preamble for other certification criteria that include C-CDA creation within its scope, we have limited the C-CDA Release 2.1 document template requirements based on the use case for each certification criterion. Therefore, some criteria (e.g., ToC) require three C-CDA templates whereas others (e.g., care plan) only require one C-CDA template. As such, we have required that C-CDA creation performance be demonstrated for the C-CDA Release 2.1 document templates required by the 2015 Edition certification criteria presented for certification. For example, if a Health IT Module only included § 170.315(e)(1) within its certificate's scope, then only the Continuity of Care Document (CCD) document template would be applicable within this criterion. Conversely, if a Health IT Module designed for the inpatient setting included § 170.315(b)(1) within its certificate's scope, then all three document templates referenced by that criterion would need to be evaluated as part of this certification criterion.

If the scope of certification includes more than one certification criterion

with C-CDA creation required, C-CDA creation performance only has to be demonstrated once for each C-CDA document template (e.g., C-CDA creation performance to the CCD template would *not* have to be demonstrated twice if the Health IT Module presents for certification to both "ToC" and the "data export" criteria).

Comments. One commenter was concerned that the proposed regulation text language "upon the entry of clinical data consistent with the Common Clinical Data Set" implies the incorrect workflow, and would only allow creation to be done while the user finishes creating or composing the C-CDA document. The commenter noted that there is an additional step between creation and sending where additional vocabulary mapping steps need to be applied.

Response. We thank the commenter for the input. We clarify that the purpose of the phrase was to provide a clear scope to the certification criterion for health IT developers. Given that the C-CDA includes many section templates to represent data outside of the data specified by the Common Clinical Data Set definition, we sought to indicate that testing would be limited to only the data within scope for the Common Clinical Data Set definition. We have modified the language in the certification criterion to more clearly reflect this scope limitation.

C-CDA Completeness

Due to past feedback from providers that indicated the variability associated with different functionalities and workflows within certified health IT can ultimately affect the completeness of the data included in a created C-CDA, we requested comment on a proposal that would result in a certification requirement to evaluate the completeness of the data included in a C-CDA. This additional requirement would ensure that the data recorded by a user in health IT is equivalent to the data included in a created C-CDA.

Comments. We received mixed comments in response to this request for comment. One commenter was supportive of the proposal. Another commenter requested clarification on whether the request for comment intended to specify how the user interface captures specific data using specific vocabulary, and was not supportive of imposing data capture requirements for this criterion. One commenter was concerned that ONC was being too prescriptive by soliciting comment on this potential requirement to test C-CDA completeness and suggested ONC test this in a sub-

regulatory manner and/or through improved conformance test tools. One commenter suggested that some C-CDA document templates do not include all information entered into an EHR for certain use cases, as some document templates are meant to include targeted and specific information for a particular setting to which a patient is being transitioned.

Response. We thank commenters for the input and, in consideration of the comments, have adopted this proposal as part of this certification criterion. As we stated in the Proposed Rule, the intent and focus of this proposal was to ensure that however data is entered into health IT—via whatever workflow and functionality—that the C-CDA output would reflect the data input and not be missing data a user otherwise recorded. We also clarify that the scope of the data for this certification criterion is limited to the Common Clinical Data Set definition. We did not intend imply and note that that this criterion does not prescribe how the user interface captures data.

Repository of C-CDA Documents

We did not receive any comments regarding our understanding that NVLAP-Accredited Testing Laboratories would retain the C-CDA files created under test and contribute them to an ONC-maintained repository. We note that we intend to implement this repository as noted in the Proposed Rule.

- *Application Access To Common Clinical Data Set*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(7) (Application access—patient selection)

2015 Edition Health IT Certification Criterion
§ 170.315(g)(8) (Application access—data category request)

2015 Edition Health IT Certification Criterion
§ 170.315(g)(9) (Application access—all data request)

We proposed a new 2015 Edition criterion at § 170.315(g)(7) that would require health IT to demonstrate it could provide application access to the Common Clinical Data Set via an application programming interface (API), and requiring that those same capabilities be met as part of the “VDT” criterion. We noted that providing API functionality could help to address many of the challenges currently faced

by individuals and caregivers accessing their health data, including the “multiple portal” problem, by potentially allowing individuals to aggregate data from multiple sources in a web or mobile application of their choice. We emphasized that the proposed approach was intended to provide flexibility to health IT developers to implement an API that would be most appropriate for its customers and allow developers to leverage existing standards that most health IT developers would already need in order to seek certification for other criteria.

Because many commenters provided feedback on the “API” criterion within the context of the “VDT” criterion and in the order of this final rule the VDT discussion comes first, we address all comments to proposed § 170.315(g)(7) here.

Comments. The HITSC recommended that we permit Health IT Modules to certify towards each of the three API scenarios (get patient identifier, get document, get discrete data) individually, while stating the expectation that Health IT developers and provider organizations should ensure that the APIs work together functionally. The HITSC also recommended providing a “sub-regulatory flexibility” certification testing approach to allow developers to achieve certification by participating in “a public-private effort that provides adequate testing and other governance sufficient to achieve functional interoperability.”

Response. We agree with the approach suggested by the HITSC to split our original proposed certification criterion into three separate certification criteria with each individual criterion focused on specific functionality. Based on prior experience with certification criteria that “lump” functionality together that can otherwise be separately performed, we believe that this additional flexibility will allow for health IT developers to be more innovative. This will enable additional modularity as part of the ONC Health IT Certification Program in the event that a health IT developer seeks to change and recertify one of the three API functionalities and leave the other two capabilities unchanged. The three certification criteria will be adopted at § 170.315(g)(7), (g)(8), and (g)(9). Each will include the documentation and terms of use requirement that was part of the single proposed criterion. Additionally, in consideration of this change and because CMS has required as part of the EHR Incentive Program Stage 3 and Modifications final rule that

providers will need to have health IT certified to both the VDT certification criterion and these three “API” criteria to meet Stage 3 Objectives 5 and 6, we have removed the API functionality embedded within the VDT certification criterion and adopted these three criteria to simplify our rule and reduce redundancy.

For the purposes of testing for each of the “API” certification criteria, a health IT developer will need to demonstrate the response (*i.e.*, output) for each of the data category requests and for the “all” request, the output according to the C-CDA in the CCD document template. For all other aspects of these certification criteria, we expect the testing would include, but not be limited to, attestation, documentation, functional demonstration, and visual inspection.

We appreciate suggestions as to a “sub-regulatory approach” and will consider whether such approaches could fit within our regulatory structure as well as lead to consistent and efficient testing and certification.

Comments. Multiple commenters voiced concern that we did not name a standard for API functionality in the Proposed Rule. Of these commenters, some suggested that we specifically name FHIR as the standard for this criterion, while others expressed concern that FHIR is not yet mature enough for inclusion in regulation, and suggested that ONC eliminate or make optional API functionality until a time when API standards have undergone more testing in the market. However, many commenters strongly supported the inclusion of API functionality for patient access, discussing the criterion’s provision of more flexibility and choice for the consumer, better facilitation of communication and education for individuals, fostering of more efficient and modern information exchange, and encouraging innovation by app developers and entrepreneurs to create better online experiences for users. Several commenters also voiced support for the approach of encouraging movement towards APIs, without locking in any specific standard, and urged ONC to maintain an open, transparent process with public input as it works with industry to identify and develop emerging standards in this space.

Response. We have adopted three new criteria as a new component of the 2015 Base EHR definition in § 170.102. We appreciate the number of detailed and thoughtful comments on this criterion, and the concerns regarding standardization. We agree with the many comments supportive of the

inclusion of API functionality for Health IT Modules, and note that in addition to enhanced flexibility for consumers and increased innovation, we believe that the “API” criteria will enable easier access to health data for patients via mobile devices, which may particularly benefit low income populations where smartphone and tablet use may be more prevalent than computer access. Regarding comments on standardization, we believe that the criterion is at an appropriate level of specificity given the ongoing development of API standards for health care, and continue to support our initial proposal to allow for a flexible approach without naming a specific standard. However, we emphasize that we intend to adopt a standards-based approach for certification in the next appropriate rulemaking and we note the existence and ongoing piloting of promising work such as the Fast Healthcare Interoperability Resources (FHIR) specification. We agree with commenters’ suggestions that ONC continue to monitor and actively participate in industry efforts to support testing of these and other emerging standards. We understand that many Health IT Modules have APIs today and providing for flexibility in the final rule will allow them to certify their existing APIs.

Security

We proposed that the API include a means for the establishment of a trusted connection with the application that requests patient data. We stated that this would need to include a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

Comments. Multiple commenters cited a need to provide security standards for this criterion while also noting that current and emerging standards, such as OAuth, are not yet tested and fully mature for inclusion in regulation. Other commenters suggested that ONC specifically name OAuth and/or some combination of OAuth, Open ID Connect, and User Managed Access (UMA) as the standards for authentication and authorization within this criterion. A few commenters cited other standards, such as HTTPS and SSL/TLS. Multiple commenters noted that the consumers of the API—the web and mobile applications—were ultimately the entities responsible for security, rather than the Health IT Module itself, and that the market for third party applications is currently unregulated.

Response. We have adopted a final criterion without the proposed requirement for registration of third party applications. Our intention is to encourage dynamic registration and strongly believe that registration should not be used as a means to block information sharing via APIs. That is, applications should not be required to pre-register (or be approved in advance) with the provider or their Health IT Module developer before being allowed to access the API. Under the 2015 Edition privacy and security (P&S) certification framework, health IT certified to the API criteria must support an application connecting to the API. The P&S certification framework for the API criteria requires that a Health IT Module certified to this criterion be capable of ensuring that: valid user credentials such as a username and password are presented (that match the credentials on file at the provider for that user); the provider can authorize the user to view the patient’s data; the application connects through a trusted connection; and the access is audited (§ 170.515(d)(1); (d)(9); and (d)(2) or (d)(10); respectively). These certification requirements should be sufficient to allow access without requiring further application pre-registration. The applicable P&S certification criteria are discussed in more detail below.

We intend to pursue a standards-based approach for this criterion in the future, but believe that providing flexibility currently is more appropriate as emerging standards continue to mature and gain traction in industry, and consistent with our overall “functional” approach to the API certification criteria at § 170.315(g)(7), (g)(8), (g)(9). We recognize and encourage the work being done to develop emerging standards in this space, including OAuth, OpenID Connect, UMA, and the Open ID Foundation’s HEART profile. Accordingly, we emphasize that the security controls mentioned in the Proposed Rule establish a floor, not a ceiling. We encourage organizations to follow security best practices and implement security controls, such as penetration testing, encryption, audits, and monitoring as appropriate, without adversely impacting a patient’s access to data, following their security risk assessment. We expect health IT developers to include documentation on how to securely deploy their APIs in the public documentation required by the certification criteria and to follow industry best practices. We also seek to clarify that a “trusted connection” means the link is encrypted/integrity

protected according to § 170.210(a)(2) or (c)(2). As such, we do not believe it is necessary to specifically name HTTPS and/or SSL/TLS as this standard already covers encryption and integrity protection for data in motion.

While we appreciate the concerns of commenters regarding privacy and security of third party applications, we note that the regulation of third party applications is outside the scope of certification, unless those applications are seeking certification as Health IT Modules. As consumer applications, third-party applications may fall under the authority of the Federal Trade Commission (FTC). In addition, if third-party applications are offered on behalf of a HIPAA covered entity or business associate, they would be governed by the HIPAA Privacy and Security Rules as applicable to those entities. We also note that the Federal Trade Commission and the National Institute of Standards and Technology (NIST) have issued guidance regarding third-party applications; we encourage third-party application developers to take advantage of these resources.¹²²

Comments. Commenters pointed out that the proposed process for certifying security & privacy requirements for the “Application Access to Common Clinical Data Set” criterion was inconsistent with the proposed privacy and security certification approach listed in Appendix A of the Proposed Rule’s preamble. The HITSC recommended that we include encryption and integrity protection as a security requirement for the “API” criterion.

Response. We agree with commentators that the approach from our prior rules and our most recent Proposed Rule were inconsistent. We have finalized an approach that standardizes the way Health IT Modules certify for privacy and security (P&S). For consistency, we have moved the trusted connection security requirements included proposed § 170.315(g)(7)(i) into two new certification criteria under § 170.315(d) and have applied them back to the three adopted “API” certification criteria as part of the 2015 Edition P&S certification framework

¹²² See, e.g., NIST Technical Considerations for Vetting 3rd Party Mobile Applications, available at http://csrc.nist.gov/publications/drafts/800-163/sp800_163_draft.pdf; FTC, Careful Connections: Building Security in the Internet of Things (Jan. 2015), available at <https://www.ftc.gov/tips-advice/business-center/guidance/careful-connections-building-security-internet-things>; FTC, Mobile App Developers: Start with Security (Feb. 2013), available at <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-app-developers-start-security>.

(§ 170.550(h)).¹²³ To be certified for the “API” criteria, a Health IT Module must certify to either Approach 1 (technically demonstrate) or Approach 2 (system documentation) for the following security criteria:

- Section 170.315(d)(1) “authentication, access control, and authorization;”
- Section 170.315(d)(9) “trusted connection;” and
- Section 170.315(d)(10) “auditing actions on health information” or § 170.315(d)(2) “auditable events and tamper resistance.”

We intended the trusted connection requirement to encompass encryption and integrity. The “trusted connection” criterion at § 170.315(d)(9) requires health IT to establish a trusted connection in accordance with the standards specified in § 170.210(a)(2) and (c)(2). We have adopted § 170.315(d)(10) “auditing actions on health information” as an abridged version of § 170.315(d)(2) “auditable events and tamper resistance” as some of the capabilities included in § 170.315(d)(2) would likely not apply to a Health IT Module certified only to the “API” criteria, such as recording the audit log status or encryption status of electronic health information locally stored on end-user devices by the technology. A Health IT Module presented for certification to the “API” criteria, depending on the capabilities it included for certification, could be certified to either § 170.315(d)(2) or (d)(10) as part of the 2015 Edition P&S certification framework.

We have removed the requirement that the API must include a means for the requesting application to register with the data source. Our intention was that APIs should support dynamic registration that does not require pre-approval before an application requests data from the API. However, from the comments received it was clear that our intention was not understood. Further, open source standards for dynamic registration are still under active development, there is currently no consensus-based standard to apply, and we do not want registration to become a barrier for use of Health IT Modules’ APIs. We are removing this requirement at this time for the purposes of certification and will consider verifying this technical capability for a potential future rulemaking.

Comments. Several commenters expressed concern that APIs may

¹²³ We refer readers to section IV.C.1 (“Privacy and Security”) of this preamble for further discussion of the 2015 Edition P&S certification framework.

increase security risks. In particular, these commenters called for security standards to specify the manner in which the API is authorized, authenticated, and how data must be secured in transit.

Response. Entities must follow federal and state requirements for security. APIs, like all technology used in a HIPAA-regulated environment, must be implemented consistent with the HIPAA Security Rule. Namely, covered entities and their business associates must perform a security risk assessment and must meet the HIPAA Security Rule standards, consistent with their risks to the administrative, technical, and physical security of the ePHI they maintain. The security safeguards required by certification establish a floor of security controls that all APIs must meet; an organization’s security risk assessment may reveal additional risks that must be addressed in the design or implementation their EHR’s particular API or they may have additional regulatory requirements for security. Therefore, users of health information technology should include APIs in their security risk analysis and implement appropriate security safeguards. We also strongly encourage health IT developers to build security into their APIs and applications following best practice guidance, such as the Department of Homeland Security’s Build Security In initiative.¹²⁴ We also reiterate that at this time, we are requiring a read-only capability—read-only capabilities may have fewer security risks because the EHR does not consume external data.

Provider organizations already transmit information outside their networks such as electronic claims submission, lab orders, and VDT messages. These transmissions may be occurring using APIs today. Therefore, provider organizations could already be implementing safeguards needed to secure APIs. We encourage providers to employ resources released by OCR and ONC, such as the Security Risk Assessment Tool¹²⁵ and the Guide to Privacy and Security of Electronic Health Information,¹²⁶ as well as the Office for Civil Rights’ website¹²⁷ to make risk-based decisions regarding their implementation of APIs and the

¹²⁴ <https://buildsecurityin.us-cert.gov/>.

¹²⁵ ONC Security Risk Assessment Tool: <http://www.healthit.gov/providers-professionals/security-risk-assessment>.

¹²⁶ ONC Guide to Privacy and Security of Electronic Health Information: <http://www.healthit.gov/sites/default/files/pdf/privacy-and-security-guide.pdf>.

¹²⁷ HHS Office for Civil Rights: <http://www.hhs.gov/ocr/office/index.html>.

selection of appropriate and reasonable security safeguards.

It is important to recognize that an API may be used to enable a patient to access data in the Designated Record Set for that individual, pursuant to 45 CFR 164.524(a)(1).¹²⁸ Additionally, the electronic tools an individual uses to handle or transport data in the individual’s custody are not required to meet the HIPAA Security Rule. Those tools cannot pose an unreasonable threat to the covered entity’s system, but the tools used by the individual themselves are not regulated by HIPAA. For example, a patient may insist that in providing an electronic copy of data about them, the email that delivers the ePHI to the patient is not encrypted.¹²⁹ A patient may also select a third party product that will receive their data through the API that is not subject to HIPAA Security Rule requirements.

Comments. Several commenters stated that APIs should align with patient privacy expectations.

Response. We appreciate the commenters’ concerns about patient privacy expectations and agree that use of APIs must align with all federal and state privacy laws and regulations. We expect APIs to be used in circumstances when consent or authorization by an individual is required, as well as in circumstances when consent or authorization by an individual is not legally required for access, use or disclosure of PHI. In other words, APIs, like faxes before them, will be used in light of the existing legal framework that already supports the transmission of protected health information, sensitive health information, and applicable consent requirements.

In circumstances where there is a requirement to document a patient’s request or particular preferences, APIs can enable compliance with such documentation requirements. The HIPAA Privacy Rule¹³⁰ permits the use of electronic documents to qualify as writings for the purpose of proving signature, e.g., electronic signatures. Electronic signatures can be captured by a patient portal or an API, absent the application of a more privacy-protective state law.

The existing legal framework would support the use of APIs to facilitate patient access to electronic health information or patient access requests

¹²⁸ 45 CFR 164.524(a)(1): <http://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013-title45-vol1-sec164-501.xml>.

¹²⁹ HHS Office for Civil Rights FAQs on HIPAA: http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/570.html.

¹³⁰ 45 CFR part 160 and Part 164, Subparts A and E.

made pursuant to 45 CFR 164.524 to transmit their information to a designated third party. For example, an individual may request a copy of their data from their provider's API using software tools of the individual's choosing. Assuming the individual has been properly authenticated and identity-proofed, the provider's obligation under HIPAA is to fulfill the "access" request through the API if that functionality is available, because that is the medium so chosen by the patient. The addition of APIs to the technical landscape of health IT does not alter HIPAA requirements, which support reliance on the established and prevailing standards for electronic proof of identity.¹³¹ This policy supports the availability of health information for treatment, payment, and health care operations (45 CFR 164.506) and leverages the progress already made to operationalize privacy laws in an electronic environment, while facilitating interoperability.

Patient Selection

We proposed that the API would need to include a means for the application to query for an identification (ID) or other token of a patient's record in order to subsequently execute data requests for that record.

Comments. Commenters noted that standardization of this requirement should include industry-accepted standards such as IHE PDQ or PIX query.

Response. Consistent with our approach throughout the "API" criteria, we decline to require a specific standard at this time, although we intend to do so in a future rulemaking. We note that the standards suggested by commenters have been adopted in industry and we encourage Health IT Modules to identify and implement any existing standards that best support the needs of their users. We have adopted these final requirements in the certification criterion adopted in § 170.315(g)(7). It includes the proposed requirement with specific conforming adjustments to be its own certification criterion. The criterion specifies that technology will need to be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. We do not presume or prescribe a particular method or amount of data by which technology developer implements its approach to uniquely identify a patient. However, we note that such information

must be included in the technical documentation also required to be made available as part of certification. Once the specific ID or other token is returned in a response, we expect and intend for the other "API" criteria discussed below to be able to use the ID or other token to then perform the data requests.

Data Requests, Response Scope, and Return Format

We proposed that the API would need to support two types of data requests and responses: "by data category" and "all." In both cases, the proposed scope for certification was limited to the data specified in the Common Clinical Data Set. For "by data category," the API would need to respond to requests for each of the data categories specified in the Common Clinical Data Set and return the full set of data for that data category. We also proposed that as the return format for the "by data category," that either XML or JSON would need to be produced. "All" requests for a specific patient would return a patient's fully populated summary record formatted in accordance with the C-CDA version 2.0.

Comments. Commenters suggested several specific changes to this criterion, including: We should clarify that access is for a specific patient; we should include a requirement that applications be able to request specific date ranges, ability to request patient lists or other identified populations; and we should remove the return format of either XML or JSON, because some APIs could return data in HL7 v2 format. For the "data category" request requirement, commenters asked that ONC clarify whether "each" means a query limited to one category at a time, or whether combinations of categories can be requested at one time. For "all" requests, some commenters suggested that this functionality should support the ability to view or download based on specific data, time, or period of time; other commenters urged us to focus first on the narrow set of capabilities initially proposed to gain experience, and add additional capabilities in future certification. Most commenters supported focusing on the CCD document to create clear expectations and enhance interoperability. Two commenters were opposed to restricting the use of C-CDA 2 to CCD document type because other document types (i.e. Transfer Summary, Referral Note and Care Plan) are very commonly used documents in the real world, and would not be available through this functionality.

Response. We expect that all three API capabilities would function

together; thus applications connecting to the API would be able to request data on a specific patient, as described in the "API—patient selection" criterion, using an obtained ID or other token. At this time, we have decided not to include an additional patient list creation requirement. However, we emphasize that this initial set of APIs represents a floor rather than a ceiling, and we expect developers to build enhanced APIs to support innovation and easier, more efficient access to data in the future.

In response to concerns regarding the return format for the data-category request, we have decided to make that requirement more flexible and have removed the specific proposed language of XML or JSON to say in the final criterion that the returned data must be in a computable (i.e., machine readable) format.

In response to comments concerning the "all-request," we clarify that the API functionality must be able to respond to requests for all of the data included in the CCDS on which there is data for patient, and that the return format for this functionality would be limited to the C-CDA's CCD document template. We believe that focusing on the CCD document template will reduce the implementation burden for health IT developers to meet this certification criterion and will help application developers connecting to Health IT Modules' APIs because they will know with specificity what document template they are going to receive.

With regard to requests for each "data category," for the purposes of certification, the technology must demonstrate that it can respond to requests for each individual data category one at a time. However, this is a baseline for the purposes of testing and certification and health IT developers are free to enable the return of multiple categories at once if they choose to build out that functionality.

Similar to our response for "VDT" criterion, we clarify that patients should be provided access to any data included in the Common Clinical Data Set.

As with the VDT requirement, we have adopted date and time filtering requirements as part of this criterion. We agree with commenters that adding this functionality to these criteria will provide clarity that patients should have certain baseline capabilities available to them when it comes to selecting the data (or range of data) they wish to access using an application that interacts with the Health IT Module's APIs. Specifically, we have adopted two timeframe requirements: First, to ensure that an application can request data

¹³¹ NIST SP 800-63-2.

associated with a specific date, and the second, to ensure that an application can request data within an identified date range, which must be able to accommodate the application requesting a range that includes all data available for a particular patient. The technology specifications should be designed and implemented in such a way as to return meaningful responses to queries, particularly with regard to exceptions and exception handling, and should make it easy for applications to discover what data exists for the patient.

Documentation and Terms of Use

We proposed that the required technical documentation would need to include, at a minimum: API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. We also stated that the terms of use must include the API's developer policies and required developer agreements so that third-party developers could assess these additional requirements before engaging in any development against the API. We also proposed that health IT developers would need to submit a hyperlink to ONC-ACBs, which the ONC-ACB would then submit as part of its product certification submission to the Certified Health IT Product List (CHPL) that would allow any interested party to view the API's documentation and terms of use.

Comments. One commenter suggested that ONC should clarify whether our intent is that terms of use would replace, include, or overlap with HIPAA privacy policies that health care providers are required to provide their patients. Another commenter voiced concern that the API-consuming application should be the party responsible for assuring effective use of the API in terms of safety, security, privacy, and accessibility. Multiple commenters suggested that ONC place certain restrictions on terms of use, including limits on any fees, copyright, or licensing requirements on APIs.

Response. We emphasize that nothing in this criterion is intended to replace federal or state privacy laws and regulations, nor the contractual arrangements between covered entities and business associates. Placing requirements or limitations on the specific content of the terms of use is beyond the scope of certification. However, we reiterate that our policy intent is to allow patients to access their data through APIs using the applications of their own choosing, and limit the creation of "walled gardens" of

applications that only interact with certain Health IT Modules. As stated previously in this preamble, we intend to require a standards-based approach to this criterion in the next appropriate rulemaking and we encourage vendors to start piloting the use of existing and emerging API standards. By requiring that documentation and terms of use be open and transparent to the public by requiring a hyperlink to such documentation to be published with the product on the ONC Certified Health IT Product List, we hope to encourage an open ecosystem of diverse and innovative applications that can successfully and easily interact with different Health IT Modules' APIs.

• *Transport Methods and Other Protocols*

We proposed two ways for providers to meet the 2015 Edition Base EHR definition using health IT certified to transport methods. The first proposed way to meet the proposed 2015 Edition Base EHR definition requirement would be for a provider to have health IT certified to § 170.315(b)(1) and (h)(1) (Direct Project specification). This would account for situation where a provider uses a health IT developer's product that acts as the "edge" and the HISP. The second proposed way would be for a provider to have health IT certified to § 170.315(b)(1) ("ToC" criterion) and (h)(2) ("Direct Project, Edge Protocol, and XDR/XDM"). This would account for situations where a provider is using one health IT developer's product that serves as the "edge" and another health IT developer's product that serves as a HISP.¹³² To fully implement this approach, we proposed to revise § 170.550 to require an ONC-ACB to ensure that a Health IT Module includes the certification criterion adopted in § 170.315(b)(1) in its certification's scope in order to be certified to the certification criterion proposed for adoption at § 170.315(h)(1). We lastly proposed to revise the heading of § 170.202 from "transport standards" to "transport standards and other protocols."

We received minimal comments on these proposals and discussed what comments we received under the "Direct Project, Edge Protocol, and XDR/XDM" certification criterion below.

• *Direct Project*

¹³² See the 2014 Edition Release 2 final rule for more discussion on such situations (79 FR 54436-38).

2015 Edition Health IT Certification Criterion § 170.315(h)(1) (Direct Project)

We proposed to adopt a certification criterion that includes the capability to send and receive according to the Applicability Statement for Secure Health Transport (the primary Direct Project specification). We noted that we previously adopted this capability for the 2014 Edition at § 170.314(b)(1), (b)(2) and (h)(1). We proposed to include as an optional capability for certification the capability to send and receive according to the Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012 ("Delivery Notification IG"). We explained that the primary Direct Project lacked certain specificity and consistency guidance such that deviations from normal message flow could result if Security/Trust Agents (STAs) implemented only requirements denoted as "must" in Section 3 of the primary Direct Project. As a result, STAs may not be able to provide a high level of assurance that a message has arrived at its destination. We further stated that 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.

Comments. Commenters overwhelmingly supported the adoption of this criterion as proposed. Many commenters also expressed strong support for the optional delivery notification provision as a means to support specific business practices. Some commenters stated that delivery notification will only work when both receiving and sending parties support the functionality and, thus, delivery notification must be required of both sending and receiving entities in order for it to work. Commenters also requested clarification regarding "ownership" and maintenance of the Direct Project, including some that recommended that "ownership" should belong to a SDO.

Response. We have adopted a revised criterion in comparison to our proposal and the related 2014 Edition certification criteria. After careful consideration of comments, we believe it is appropriate to adopt the Applicability Statement for Secure Health Transport, Version 1.2 (August 3,

2015).¹³³ This new version of the specification includes updates that improve interoperability through the clarification of requirements that have been subject to varying interpretations, particularly requirements around message delivery notifications. This version also clarifies pertinent requirements in the standards underlying the Applicability Statement for Secure Health Transport. Migration to this newer version will provide improvements for exchange of health information and should have minor development impacts on health IT developers. Further, we expect that many developers and technology organizations that serve as STAs will quickly migrate to version 1.2 due to its improvements. We note, for certification to this criterion, we have made it a requirement to send and receive messages in only “wrapped” format even though the specification (IG) allows use of “unwrapped” messages. This requirement will further improve interoperability among STAs, while having minor development impact on health IT developers.

We have also adopted as a requirement for this criterion the Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012. While we proposed this IG as an optional provision, we agree with commenters that this functionality must be required to best support interoperability and exchange, particularly for both sending and receiving parties. As we stated in the 2014 Edition Release 2 proposed rule (79 FR 10914–915), the capabilities in this IG provide implementation guidance enabling HISPs to provide a high level of assurance to senders that a message has arrived at its destination, a *necessary* component to interoperability.

We appreciate the recommendations and questions regarding “ownership” of the Direct specifications. We clarify that although ONC played a significant role in the creation and coordination of the Direct specifications that ONC does *not* “own” them. Rather, the specifications are publicly available and we view them as maintained by the community of stakeholders who have and continue to support the Direct specifications. To that end, as a participant in this community, we have been working with other stakeholders to locate an appropriate SDO who can maintain and mature these specifications over the

long term. We believe this step is both necessary and critical for Direct specifications to be well maintained and industry supported over time.

• *Direct Project, Edge Protocol, and XDR/XDM*

2015 Edition Health IT Certification Criterion

§ 170.315(h)(2) (Direct Project, Edge Protocol, and XDR/XDM)

We proposed a 2015 Edition “Direct, Edge Protocol, and XDR/XDM” certification criterion that included three distinct capabilities. The first proposed capability focused on technology’s ability to send and receive according to the Applicability Statement for Secure Health Transport (the primary Direct Project specification). The second proposed capability focused on technology’s ability to send and receive according to both Edge Protocol methods specified by the standard adopted in § 170.202(d). The third proposed capability focused on technology’s ability to send and receive according to the XDR and XDM for Direct Messaging Specification. We noted that these three capabilities were previously adopted as part of the 2014 Edition, including through the 2014 Edition and 2014 Edition Release 2 final rules, and we reminded health IT developers that best practices exist for the sharing of information and enabling the broadest participation in information exchange with Direct.¹³⁴

Comments. Commenters overwhelmingly supported the adoption of this criterion as proposed. A commenter suggested that the primary Direct Project specification should only be included in the Direct Project certification criterion (§ 170.315(h)(1)). A commenter requested clarification on the anticipated advantage(s) of certifying with XDR/XDM. A commenter stated some systems are still using SMTP and IMAP. Another commenter stated that while certified Health IT Modules may implement Direct Edge protocols there is no requirement for HISPs to adopt the protocol. Commenters also requested clarification regarding “ownership” and maintenance of the Direct project, with some recommending that “ownership” should belong to a SDO.

Response. We have adopted this as a revised criterion in comparison to our proposal and the related 2014 Edition certification criteria. After careful consideration of comments, we believe it is appropriate to adopt the

Applicability Statement for Secure Health Transport, Version 1.2 (August 3, 2015).¹³⁵ This new version of the specification includes updates that improve interoperability through the clarification of requirements that have been subject to varying interpretations, particularly requirements around message delivery notifications. This version also clarifies pertinent requirements in the standards underlying the Applicability Statement for Secure Health Transport. Migration to this newer version will provide improvements for exchange of health information and should have minor development impacts on health IT developers. Further, we expect that many developers and technology organizations that serve as STAs will quickly migrate to version 1.2 due to its improvements. For certification to this criterion, we have made it a requirement to send and receive messages in only “wrapped” format even though the specification (IG) allows use of “unwrapped” messages. This requirement will further improve interoperability among STAs while having minor development impact on health IT developers.

We have also adopted as a requirement for this criterion the Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012. While we proposed this IG as an optional provision, we agree with commenters that this functionality must be required to best support interoperability and exchange, particularly for both a sending and receiving HISP. As we stated in the 2014 Edition Release 2 proposed rule (79 FR 10914–915), the capabilities in this IG provide implementation guidance enabling HISPs to provide a high level of assurance to senders that a message has arrived at its destination, a *necessary* component to interoperability.

We require the use of XDR/XDM to support interoperability and ensure that certain messages packaged using XDR/XDM can be received and processed. This is the same approach we required with the 2014 Edition. We also refer readers to the “ToC” certification criterion discussed earlier in this preamble for further explanation of the interoperability concerns related to the use of XDR/XDM. We clarify for commenters that for health IT to be certified to this criterion it must be able to support both of the Edge Protocols

¹³³ <http://wiki.directproject.org/file/view/Applicability%20Statement%20for%20Secure%20Health%20Transport%20v1.2.pdf/556133893/Applicability%20Statement%20for%20Secure%20Health%20Transport%20v1.2.pdf>.

¹³⁴ <http://wiki.directproject.org/Best+Practices+for+Content+and+Workflow>.

¹³⁵ <http://wiki.directproject.org/file/view/Applicability%20Statement%20for%20Secure%20Health%20Transport%20v1.2.pdf/556133893/Applicability%20Statement%20for%20Secure%20Health%20Transport%20v1.2.pdf>.

methods referenced in the Edge IG version 1.1 (i.e., the “IHE XDR profile for Limited Metadata Document Sources” edge protocol or an SMTP-focused edge protocol (SMTP alone or SMTP in combination with either IMAP4 or POP3)).

We note that even though the Edge Protocol requires support for XDS limited metadata, XDR/XDM supports capability to transform messages using full metadata wherever appropriate. Therefore, we require that a Health IT Module must support both the XDS Metadata profiles (Limited and Full), as specified in the underlying IHE specifications, to ensure that the transformation between messages packaged using XDR/XDM are done with as much appropriate metadata as possible.

This criterion requires the three capabilities specified (Direct Project specification, Edge Protocol compliance, and XDR/XDM processing) because it must support interoperability and all potential certified exchange options as well as support a provider in meeting the Base EHR definition. As we discussed above, a provider could use an “independent” HISP to meet the Base EHR definition. In such a case, the HISP would need to be certified to this criterion in order for the provider to use it to meet the Base EHR definition, which is part of the CEHRT definition under the EHR Incentive Programs. Therefore, there is incentive for a HISP to be certified to this criterion.

Please see our prior response regarding the “ownership” of the Direct

specifications under the “Direct Project” certification criterion.

4. Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria

We have previously defined gap certification at 45 CFR 170.502 as the certification of a previously certified Complete EHR or EHR Module(s) to: (1) all 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) all 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 health IT to be certified to only the differences between certification criteria editions rather than requiring health IT to be fully retested and recertified to certification criteria (or capabilities) 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 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, we included a table in the Proposed Rule to provide a crosswalk of the

proposed “unchanged” 2015 Edition certification criteria to the corresponding 2014 Edition certification criteria (80 FR 16868). We noted that with respect to the 2015 Edition certification criteria at § 170.315(g)(1) through (g)(3) that gap certification eligibility for these criteria would be fact-specific and would depend on any modifications made to the specific certification criteria to which these “paragraph (g)” certification criteria apply.

Comments. We did not receive specific comments on the gap certification eligibility table or our described gap certification policy.

Response. We have revised the proposed “gap certification eligibility” table to reflect the adopted 2015 Edition certification criteria discussed in section III.A.3 of this preamble. Table 6 below provides a crosswalk of “unchanged” 2015 Edition certification criteria to the corresponding 2014 Edition certification criteria. These 2015 Edition certification criteria have been identified as eligible for gap certification. We note that with respect to the 2015 Edition certification criteria at § 170.315(g)(1) (“automated numerator recording”) and (g)(2) (“automated measure calculation”), a gap certification eligibility determination would be fact-specific and depend on any modifications to the certification criteria to which these criteria apply and relevant Stage 3 meaningful use objectives and measures.

TABLE 6—GAP CERTIFICATION ELIGIBILITY FOR 2015 EDITION HEALTH IT CERTIFICATION CRITERIA

2015 Edition		2014 Edition	
Regulation section 170.315	Title of regulation paragraph	Regulation section 170.314	Title of regulation paragraph
(a)(1)	Computerized provider order entry—medications.	(a)(1)	Computerized provider order entry
		(a)(18)	Computerized provider order entry—medications
(a)(2)	Computerized provider order entry—laboratory.	(a)(1)	Computerized provider order entry
		(a)(19)	Computerized provider order entry—laboratory
(a)(3)	Computerized provider order entry—diagnostic imaging.	(a)(1)	Computerized provider order entry
		(a)(20)	Computerized provider order entry—diagnostic imaging
(a)(4)	Drug-drug, drug-allergy interaction checks for CPOE.	(a)(2)	Drug-drug, drug-allergy interaction checks
(a)(7)	Medication list	(a)(6)	Medication list
(a)(8)	Medication allergy list	(a)(7)	Medication allergy list
(a)(10)	Drug-formulary and preferred drug list checks	(a)(10)	Drug-formulary checks
(a)(11)	Smoking status	(a)(11)	Smoking status
(d)(1)	Authentication, access control, and authorization.	(d)(1)	Authentication, access control, and authorization
(d)(3)	Audit report(s)	(d)(3)	Audit report(s)
(d)(4)	Amendments	(d)(4)	Amendments
(d)(5)	Automatic access time-out	(d)(5)	Automatic log-off
(d)(6)	Emergency access	(d)(6)	Emergency access
(d)(7)	End-user device encryption	(d)(7)	End-user device encryption
(d)(11)	Accounting of disclosures	(d)(9)	Accounting of disclosures

TABLE 6—GAP CERTIFICATION ELIGIBILITY FOR 2015 EDITION HEALTH IT CERTIFICATION CRITERIA—Continued

2015 Edition		2014 Edition	
Regulation section 170.315	Title of regulation paragraph	Regulation section 170.314	Title of regulation paragraph
(f)(3)	Transmission to public health agencies—reportable laboratory tests and values/results.	(f)(4)	Inpatient setting only—transmission of reportable laboratory tests and values/results

5. Not Adopted Certification Criteria

This section of the preamble discusses proposed certification criteria included in the Proposed Rule that we have not adopted and requests for comments on potential certification criteria included in the Proposed Rule. We summarize the comments received on these proposed criteria and requests for comments and provide our response to those comments.

• *Vital Signs, Body Mass Index, and Growth Charts*

We proposed to adopt a 2015 Edition “vital signs, BMI, and growth charts” certification criterion that was revised in comparison to the 2014 Edition “vital signs, BMI, and growth charts” criterion (§ 170.314(a)(4)). Specifically, we proposed to: (1) Expand the types of vital signs for recording;¹³⁶ (2) require that each type of vital sign have a specific LOINC® code attributed to it; (3) that The Unified Code of Units of Measure, Revision 1.9, October 23, 2013 (“UCUM Version 1.9”)¹³⁷ be used to record vital sign measurements; and (4) that certain metadata accompany each vital sign, including date, time, and measuring- or authoring-type source. In providing this proposal, we stated awareness that several stakeholder groups are working to define unique, unambiguous representations/ definitions for vital signs along with structured metadata to increase data standardization for consistent representation and exchange. To ensure consistent and reliable interpretation when information is exchanged, we stated that vital signs should be captured natively. In addition, we proposed “optional” pediatric vital signs for health IT to electronically record, change, and access. With regard to the proposed metadata, we requested comment on additional information that we should consider for inclusion and the best available standards for representing the metadata consistently and unambiguously. We also requested

comment on the on the feasibility and implementation considerations for proposals that rely on less granular LOINC® codes for attribution to vital sign measurements and the inclusion of accompanying metadata. In the Proposed Rule’s section III.B.3 (“Common Clinical Data Set”), we stated that vital signs would be represented in same manner for the “Common Clinical Data Set” definition as it applies to the certification of health IT to the 2015 Edition, with the exception of the proposed optional vital signs.

Comments. We received mixed feedback to the overall proposal, with many commenters suggesting that (1) ONC should not be mandating how vital signs are recorded natively within certified Health IT Modules, and (2) the proposed approach to require recording of vital signs using a less granular LOINC® code with associated metadata was not a mature or the right approach for ensuring semantic interoperability. Many commenters suggested that ONC should only specify how vital signs are exchanged for the Common Clinical Data Set.

Concerning the proposal to specify how vital signs are recorded natively in a health IT system, commenters noted that there would be workflow and usability issues, such as requiring the user to enter in metadata every time a vital sign is taken. As vital signs are routinely taken as a part of every patient visit in many provider settings, this could be burdensome and time-consuming.

Regarding the proposed approach to record vital signs using a less granular LOINC® code with associated metadata, commenters had a number of concerns. Some commenters were concerned that LOINC® was designed as a pre-coordinated code system (e.g., some LOINC® codes for vital signs are pre-specified to the site of vital sign measurement, method of vital sign measurement, and/or device used to take vital sign), but that our proposal to use a less granular code with associated metadata to assist with interpretation would treat LOINC® as a post-coordinated code system. Since LOINC® does not include specific syntax rules,

our proposed method could lead to data integrity issues and patient safety concerns. Commenters suggested that the industry is working to define a methodology for structured data capture through initiatives like the S&I Framework Structured Data Capture Initiative,¹³⁸ and that ONC should not adopt requirements for structured data capture as part of certification until there is a consensus-based way forward. A few commenters were concerned that the metadata could be lost or hidden from the user’s view when exchanged, resulting in the receiving user’s inability to accurately and safely interpret the vital sign measurement.

Some commenters noted that SNOMED CT® is the international standard used for vital signs. One commenter noted that IHE is working with the Department of Veterans Affairs and other stakeholders to create a utility that would allow conversion from SNOMED CT® to LOINC® or to make data accessible from other countries that use SNOMED CT® for vital signs.

Many commenters suggested that the complexity of the proposed approach for recording vital signs with metadata would require extensive rework and mapping of existing systems resulting in little additional benefit for workflow, usability, and semantic interoperability. As such, commenters stated there was little incentive to certify to the proposed criterion for vital signs as it was not proposed as a requirement for participation in the EHR Incentive Programs. Commenters also noted that most 2014 Edition certified health IT capture vital signs data in different methods based on the product and provider setting, but all of them still support the exchange of vital signs as specified by the industry-accepted C-CDA standard. Thus, most health IT already supports mapping to accepted industry standards for exchange today.

Response. We thank commenters for the thoughtful and detailed feedback. We agree with commenters’ concerns

¹³⁶ Per 80 FR 16818: Systolic blood pressure, diastolic blood pressure, body height, body weight measured, heart rate, respiratory rate, body temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index (BMI) [ratio], and mean blood pressure.

¹³⁷ <http://unitsofmeasure.org/trac/>.

¹³⁸ <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CCUQFjAA&url=http%3A%2F%2Fwiki.si-framework.org%2FStructured%2BData%2BCapture%2BInitiative&ei=I3KiVYW-MIKU-AH0kbjwCg&usq=AFQjCNFOiejjmvMMPbgBjd2zJ3igsdJVbw&sig2=GESy7uftrinE-ohpXqMQjw>.

regarding the proposed approach to record vital signs natively within a certified Health IT Module using less specific LOINC® codes and associated metadata. Our long-term goal is for a vital sign measurement to be semantically interoperable during exchange and thereby retain its meaning and be correctly interpretable by a receiving system user. As vital signs data relates to clinical decision support (CDS) and other quality reporting improvement tools, we continue to believe that vital signs should be consistently and uniformly captured in order to apply industry-developed CDS and CQM standards. However, as noted by commenters, the proposed approach does not fully achieve these goals and does not offer an added benefit to the current 2014 Edition approach of requiring vital signs exchange using industry standards and capture in a standards-agnostic manner. We expect the industry to develop a consensus-based approach for structured data capture, including for vital signs, and we will continue to support these processes in consideration of a future rulemaking. Given these considerations, we have not adopted a 2015 Edition “vital signs, BMI, and growth charts” certification criterion at this time, as we believe there is no added certification value for capturing vital signs in either the proposed manner or in a simply standards-agnostic manner.

- *Image Results*

We proposed to adopt a 2015 Edition “image results” certification criterion that was unchanged in comparison to the 2014 Edition “image results” criterion (§ 170.314(a)(12)).

Comments. The majority of commenters supported this criterion as proposed, but some commenters questioned why health IT developers would seek certification to this criterion and why providers would adopt health IT certified to this criterion because it did not support an objective or measure of the proposed EHR Incentive Programs Stage 3 or another program requirement. Some commenters also questioned the value of this criterion without a required standard, with a few commenters recommending the adoption of the Digital Imaging and Communication in Medicine (DICOM) standard.

Response. We have not adopted this certification criterion as part of the 2015 Edition at this time. We have considered public comments and no longer believe there is sufficient value in making this criterion available for certification as proposed. The criterion was proposed with functional requirements that do not advance functionality beyond the

2014 Edition “image results” criterion, support interoperability, nor serve an identified HHS or other program requiring the use of health IT certified to this functionality. In the response to the commenters recommending DICOM as the standard we should adopt, we will further assess whether there is an appropriate use case for the adoption of a certification criterion that requires the use of the DICOM standard as part of any future rulemaking. However, for the particular criterion we proposed, we refer readers to our prior thoughts on the appropriateness of adopting DICOM (77 FR 54173).

- *Family Health History—Pedigree*

In the Proposed Rule, we proposed a 2015 Edition “family health history—pedigree” certification criterion that required health IT to enable a user to create and incorporate a patient’s FHH according to HL7 Pedigree standard and the HL7 Pedigree IG, HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1.¹³⁹

Comments. While some commenters supported adoption of this functionality and criterion, many commenters expressed concerns about the standard and IG. Commenters stated that there has been very little adoption of the Pedigree standard and IG. Commenters also expressed specific concerns about the standard and IG. Commenters noted that the standard is out of date (not been updated since 2009) and not in sync with HL7 V3-based standards. Commenters also stated that the IG was immature and had not been updated since 2013. In particular, commenters noted that the W3C XML schema language cannot represent all constraints expressed in the base specifications referenced in the IG and that there was a lack of clear guidance on interactions and appropriate implementations, which would likely lead to inconsistent implementations. Overall, commenters suggested that a criterion not be adopted with the Pedigree standard and associated IG until the standard and IG have been appropriately updated, including addressing the interoperability interactions that need to be supported, matured, and widely adopted.

Response. We thank commenters for their detailed feedback. We have not adopted this criterion as part of the 2015 Edition at this time. We agree with commenters that further effort is necessary to address their concerns before adoption of this criterion and associated standards. We intend to follow up with relevant stakeholders to

¹³⁹ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=301.

address these concerns and will consider whether it is appropriate to include such a criterion and associated standards in a future rulemaking as HHS’ work to support the Precision Medicine Initiative matures.¹⁴⁰

- *Patient List Creation*

We proposed to adopt a 2015 Edition “patient list creation” certification criterion that was unchanged in comparison to the 2014 Edition “patient list creation” criterion (§ 170.314(a)(14)) and explained the expectation that a Health IT Module must demonstrate its capability to use at least one of the more specific data categories included in the “demographics” certification criterion (§ 170.315(a)(5)) (e.g., sex or date of birth).

Comments. The majority of commenters supported this criterion as proposed, but some commenters questioned why health IT developers would seek certification to this criterion and why providers would adopt health IT certified to this criterion because it did not support an objective or measure of the proposed EHR Incentive Programs Stage 3 or another program requirement. Conversely, some commenters suggested that we adopt a “patient list creation” criterion that had more functionality that would be valuable to providers. These commenters suggested that the criterion included required functionality to select, sort, and create patient lists on, for example: on all patient demographics, vital signs, orders, and referrals, and allergies beyond medication allergies. Commenters stated that such enhanced functionality would improve patient tracking and the monitoring of health disparities.

Response. We have not adopted this certification criterion as part of the 2015 Edition at this time. We have considered public comments and no longer believe there is sufficient value in making this criterion available for certification as proposed. The criterion was proposed with limited functionality that did not go beyond the 2014 Edition “patient list creation” criterion. Further, as proposed, it does not serve an identified HHS or other program. We will, however, consider the comments recommending more enhanced functionality as we consider certification criteria for future rulemaking.

- *Electronic Medication Administration Record*

We proposed to adopt a 2015 Edition electronic medication administration record (eMAR) certification criterion that was unchanged in comparison to

¹⁴⁰ <http://www.nih.gov/precisionmedicine/>.

the 2014 Edition “eMAR” criterion (§ 170.314(a)(16)).

Comments. The majority of commenters supported this criterion as proposed, but some commenters questioned why health IT developers would seek certification to this criterion and why providers would adopt health IT certified to this criterion because it did not support an objective or measure of the proposed EHR Incentive Programs Stage 3 or another identified program requirement. A few commenters requested clarification as to whether bar-code scanning is required to meet this criterion, with a couple of commenters recommending that bar-code scanning be part of this criterion to improve patient safety.

Response. We have not adopted this certification criterion as part of the 2015 Edition at this time. We have considered public comments and no longer believe there is sufficient value in making this criterion available for certification as proposed. The criterion was proposed with functional requirements that do not advance functionality beyond the 2014 Edition “eMAR” criterion, support interoperability, nor serve an identified program requiring the use of health IT certified to this functionality. We will consider whether we should propose the same or a more enhanced eMAR certification criterion in future rulemaking, including giving consideration to the value of identifying or requiring specific assistive technologies (e.g., bar-code scanning) for demonstrating compliance with the functional requirements of the criterion.

- *Decision Support—Knowledge Artifact; and Decision Support—Service*
- *Decision Support—Knowledge Artifact*

In the Proposed Rule, we proposed to adopt a new 2015 Edition “decision support—knowledge artifact” certification criterion that, for the purposes of certification, would require health IT to demonstrate that it could electronically send and receive clinical decision support (CDS) knowledge artifacts in accordance with a Health eDecisions (HeD) standard. To assist the industry in producing and sharing machine readable files for representations of clinical guidance, we proposed to adopt the HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 DSTU (July 2014) (“HeD standard Release 1.2”)¹⁴¹ and to require health IT to demonstrate it can electronically send and receive a CDS artifact formatted in the HeD standard

¹⁴¹ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=337.

Release 1.2. We requested comment on specific types of CDS Knowledge Artifacts for testing and certification to the HeD standard Release 1.2, and on standards’ versions to consider as alternative options, or for future versions of this certification criterion, given the ongoing work to harmonize CDS and quality measurement standards.

- *Decision Support—Service*

In the Proposed Rule, we proposed to adopt a new 2015 Edition “decision support—service” certification criterion that, for the purposes of certification, would require health IT to demonstrate that it could electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with an HeD standard and the associated HL7 Implementation Guide: Decision Support Service, Release 1.1 (March 2014), US Realm DSTU Specification.¹⁴² We specified that health IT would need to demonstrate the ability to send and receive electronic clinical guidance according to the interface requirements defined in Release 1.1. We requested comment on alternative versions of standards and on future versions of this certification criterion to advance the work to harmonize CDS and quality measurement standards.

We have summarized and responded to comments on these “decision support” criteria together as the referenced HeD standards were developed by one S&I initiative to address two use cases, we received similar comments on both proposals, and have determined to not adopt both criteria.

Comments. Many commenters supported the overall goals of the HeD standards to provide standardized ways to exchange decision support artifacts and request decision support information. However, these same commenters recommended ONC not adopt these criteria because of the ongoing work to develop harmonized CDS and clinical quality measure (CQM) standards through the Clinical Quality Framework Standards & Interoperability (S&I) Framework Initiative.¹⁴³ Commenters noted that the harmonized standards are expected to offer clinical and operational improvements for quality improvement over existing standards. These commenters also stated that they expect health IT developers and providers to dedicate

¹⁴² http://www.hl7.org/documentcenter/public/standards/dstu/HL7_DSS_IG%20_R1_1_2014MAR.zip.

¹⁴³ <http://wiki.siframework.org/Clinical+Quality+Framework+Initiative>.

resources to adopting the harmonized standards upon their completion. Therefore, these commenters stated that they do not intend to adopt the HeD standards because the standards are based on a different data model (the Virtual Medical Record or vMR) than the anticipated harmonized CDS and CQM standards. A few commenters noted that they did not support any proposal to offer certification for functionalities or standards that did not directly support a requirement of the proposed the EHR Incentive Programs Stage 3.

Response. We thank commenters for their thoughtful feedback. We acknowledge that the overall direction of health IT developers and providers is to continue to support and eventually adopt the harmonized CDS and CQM standards. Therefore, we agree with commenters that meeting the proposed “decision support” criteria and HeD standards would likely be inconsistent with this overall direction and require inefficient use of resources. As such, we also agree with comments that few, if any, health IT developers would get certified to the proposed criteria and very few providers would demand CDS functionality using the HeD standards. Accordingly, we have not adopted these certification criteria. We will continue to monitor the development and implementation of the harmonized CDS and CQM standards; and will consider whether to propose certification criteria that include these standards in a future rulemaking.

- *Incorporate Laboratory Tests and Values/Results*

We proposed to adopt a 2015 Edition “incorporate laboratory tests and values/results” certification criterion that was revised in comparison to the 2014 Edition “incorporate laboratory tests and values/results” criterion (§ 170.314(b)(5)). We proposed to adopt and include the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (“LRI Release 2”) in the final 2015 Edition “transmission of laboratory test reports” criterion for the ambulatory setting. We explained that the LRI Release 2 addresses errors and ambiguities found in LRI Release 1 and harmonizes interoperability requirements with other laboratory standards we proposed to adopt in this final rule (e.g., the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, DSTU Release 2, US Realm, 2013).

We proposed that a Health IT Module would be required to display 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 intervals or normal 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 also proposed to require a Health IT Module to be able to use, at a minimum, LOINC[®] version 2.50 as the vocabulary standard for laboratory orders.

Comments. We received mixed comments on this proposed certification criterion. Some commenters generally supported adopting the LRI Release 2 IG. Other commenters also expressed support for inclusion of LOINC[®]. One commenter pointed out potential issues with the use of LOINC[®] as its use may conflict with CLIA reporting requirements for the test description and that in some cases a textual description from the laboratory must be displayed for CLIA reporting. This commenter encouraged the harmonization of requirements with CMS and CDC for CLIA reporting to eliminate potential conflicts. Some commenters expressed concerns that the proposed LRI Release 2 IG was immature and noted additional pilots and potential refinements should be pursued before requiring adoption of the IG for certification.

Response. We have not adopted this certification criterion as part of the 2015 Edition at this time. We have made this determination based on a number of factors, including (among other aspects) that this criterion is no longer referenced by the EHR Incentive Programs and that the best versions of the IGs (LRI and EHR–S Functional Requirements for LRI) that could be associated with this criterion are not sufficiently ready. We agree with commenters regarding the LRI Release 2 IG lack of readiness for widespread adoption. We believe, however, that there is great promise and value in the LRI Release 2 IG for improving the interoperability of laboratory test results/values, the electronic exchange of laboratory test results/values, and compliance with CLIA for laboratories. To that end, we emphasize that we remain committed to continued collaboration with stakeholders to take the necessary steps to support widespread adoption of this IG, including the availability of test tools for industry use. As necessary and feasible, we also remain interested in supporting appropriate pilots for the IG.

EHR–S Functional Requirements LRI IG/Testing and Certification Requirements—Request for Comment

We sought comment on the HL7 EHR–S Functional Requirements for the V2.5.1 Implementation Guide: S&I Framework Lab Results Interface R2, Release 1, US Realm, Draft Standard for Trial Use, Release 1 (“EHR–S IG”), under ballot reconciliation with HL7¹⁴⁴ in describing the requirements related to the receipt and incorporation of laboratory results for measuring conformance of a Health IT Module to LRI Release 2. We also requested comment on uniform testing and certification approaches, specifically for the EHR–S IG.

Comments. Commenters stated that while progress has been made with the EHR–S IG, the standard has not yet been finalized and remains unproven. One commenter requested that we consider this IG for inclusion in a later edition of certification. Some commenters noted that the functional requirements would only govern a Health IT Module’s ability to receive specific laboratory result content, and there is no corresponding guarantee that a laboratory system will send well-formatted results using the EHR–S IG. Another commenter recommended that additional State variation and certification needs be accounted for in the IG. A commenter stated that the HL7 Allergies and Intolerances Workgroup¹⁴⁵ will produce standards on allergies and intolerances and that these standards should be utilized in expanding a future or revised version of the EHR–S IG to addresses genotype-based drug metabolizer rate information appropriately.

Response. We thank commenters for their feedback. We have not adopted the EHR–S IG primarily because we have not adopted this certification criterion. We also agree with commenters that the IG is not yet ready for adoption. The comments we received will be used to inform any future rulemaking related to LRI Release 2 and EHR–S IG.

• Transmission of Laboratory Test Reports

We proposed to adopt a 2015 Edition “transmission of laboratory test reports” certification criterion that was revised in comparison to the 2014 Edition “transmission of electronic laboratory tests and values/results to ambulatory

providers” criterion (§ 170.314(b)(6)). We stated that we renamed the criterion to more clearly indicate its availability for the certification of health IT used by any laboratory. We proposed to adopt and include the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (“LRI Release 2”) in the criterion and discussed our rationale for its inclusion in the 2015 Edition “incorporate laboratory tests and values/results.” We further explained that inclusion of this standard for certification should not only facilitate improved interoperability of electronically sent laboratory test reports, but also facilitate laboratory compliance with CLIA as it relates to the incorporation and display of test results in a receiving system. We also proposed to require a Health IT Module to be able to use, at a minimum, LOINC[®] version 2.50 as the vocabulary standard.

Comments. We received similar comments to those received for the proposed “incorporate laboratory tests and values/results” certification criterion described above (*i.e.*, some general support for adoption and other commenters expressed concern). In regard to expressed concerns, as recited under “incorporate laboratory tests and values/results” certification criterion, commenters stated that the proposed LRI Release 2 IG was immature and noted additional pilots and potential refinements should be pursued before requiring adoption of the IG for certification. Commenters also expressed concern with the use of LOINC[®] in relation to CLIA requirements. One commenter requested that data provenance requirements be included in the standard and/or the criterion.

Response. We have not adopted this certification criterion as part of the 2015 Edition at this time. We have made this determination based on the same factors recited for the proposed 2015 Edition “incorporate laboratory tests and values/results” certification criterion as this criterion is similarly situated as discussed below. This criterion is no longer referenced by the EHR Incentive Programs and the best version of the LRI IG that could be associated with this criterion is not sufficiently ready. We agree with commenters regarding the LRI Release 2 IG lack of readiness for widespread adoption. We believe, however, as stated under the “incorporate laboratory tests and values/results” certification criterion response to comments, that there is great promise and value in the LRI Release 2 IG for improving the

¹⁴⁴ <http://www.hl7.org/participate/onlineballoting.cfm?ref=nav#nonmember>. Access to the current draft of the EHR–S IG is freely available for review during the public comment period by establishing an HL7 user account.

¹⁴⁵ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=308.

interoperability of laboratory test results/values, the electronic exchange of laboratory test results/values, and compliance with CLIA for laboratories. To that end, we emphasize that we remain committed to continued collaboration with stakeholders to take the necessary steps to support widespread adoption of this IG, including the availability of test tools for industry use. As necessary and feasible, we also remain interested in supporting appropriate pilots for the IG.

• *Accessibility Technology Compatibility*

We proposed to adopt a new 2015 Edition “accessibility technology compatibility” certification criterion that would offer health IT developers that present a Health IT Module for certification to one or more of the clinical, care coordination, and patient engagement certification criteria listed in proposed § 170.315(a), (b), or (e) the opportunity to have their health IT demonstrate compatibility with at least one accessibility technology for the user-facing capabilities included in the referenced criteria. By “opportunity,” we noted that we meant that the proposed criterion would be available for certification but not required (*i.e.*, by the ONC Certification Program or the EHR Incentive Programs). We explained that to meet this proposed certification criterion, a Health IT Module would need to demonstrate that the capability is *compatible* with at least one accessibility technology that provides text-to-speech functionality to meet this criterion. We noted that an accessibility technology used to meet this criterion would also *not* be “relied upon” for purposes of § 170.523(f). However, we stated that it would need to be identified in the issued test report and would ultimately be made publicly available as part of the information ONC-ACBs are required to report to ONC for inclusion on the CHPL so that users would be able to identify the accessibility technology with which the certified Health IT Module demonstrated its compatibility.

We sought comment on the extent to which certification to this criterion would assist in complying with Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and other applicable federal (e.g., Section 508 of the Rehabilitation Act of 1973) and state disability laws. We also sought comment on whether certification to this criterion *as proposed* would serve as a valuable market distinction for health IT developers and consumers (e.g., “Health IT Module with certified accessibility features”).

Comments. Some commenters supported the concept of health IT being compatible with accessibility technology. Conversely, other commenters stated that complying with the criterion would be burdensome and would effectuate policy that should not be part of certification. A few commenters contended that text-to-speech capabilities would be costly to implement organization-wide and are not frequently appropriate for many health care workflows, particularly when considering privacy issues. A few commenters suggested that this criterion should include other assistive technology beyond screen readers. One commenter stated that many operation systems are already equipped with accessibility features.

Response. We thank commenters for their feedback. We have not adopted this certification criterion as part of the 2015 Edition at this time. We believe additional research is necessary into the appropriate accessibility technologies that should be referenced by such a criterion and could be supported by a testing infrastructure.

We also believe further research or evidence is needed to determine whether customers would make purchasing decisions based on whether a health IT product was *certified* as being compatible with a text-to-speech technology or simply based on whether a health IT product is compatible with the desired accessibility technology (e.g., Braille capability). In this regard, we did not propose that health IT must have certain accessibility capabilities beyond text-to-speech and, more importantly, that it must be certified to this criterion. Therefore, we have not adopted the proposed criterion.

We do, however, believe that certification can currently support the accessibility of health IT through other means. As such, we have adopted the proposed “accessibility-centered design” certification criterion. We refer readers to section III.A.3 of this preamble for further discussion of this criterion. Independent of this certification requirement, we remind health IT developers seeking certification and providers using certified health IT of their independent obligations under applicable federal civil rights laws, including Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act that require covered entities to provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

• *SOAP Transport and Security Specification and XDR/XDM for Direct Messaging*

We proposed to adopt a 2015 Edition “SOAP Transport and Security Specification and XDR/XDM for Direct Messaging” certification criterion that included the capability to send and receive according to the Transport and Security Specification (also referred to as the SOAP-Based Secure Transport RTM) and its companion specification XDR and XDM for Direct Messaging Specification. We noted that we previously adopted these capabilities for the 2014 Edition at § 170.314(b)(1), (b)(2) and (h)(3).

Comments. We received comments in support of the proposed certification criterion. One commenter suggested that support of XDM should be eliminated and replaced with a translation solution. We received also received a number of comments from the Immunization Information System (IIS) community noting their reliance on SOAP as the recommended transport mechanism for exchange of immunization information in many jurisdictions.

Response. We thank commenters for their feedback. We have not adopted this certification criterion as part of the 2015 Edition at this time. The SOAP specification was originally adopted as an alternative to, or for use in conjunction with, the Direct Project specification. The goal was to offer more certified ways to support the EHR Incentive Program Stage 2 meaningful use transition of care/exchange measure, which required the use of certified technologies in the transmission of health information. There is no longer an explicit need for certification to SOAP because the corresponding health information exchange objectives in the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register** permit any transport mechanism (*i.e.*, not necessarily the use of a certified transport method). In addition, as part of SOAP testing under the ONC Health IT Certification Program, only base SOAP standards, such as the web services standards (WS-*) are tested. For implementation, health IT systems have to layer in additional profiles (IHE based such as XDS) and IGs (e.g., NwHIN specs for patient discovery, query for documents, and retrieve documents) that utilize SOAP. The current testing for SOAP does not test for these additional standards since there has not been a convergence in the industry for a concise set of IGs. Thus, the current testing of SOAP does not provide the rigor or assurance to health IT users that

systems using SOAP will ultimately enable them to exchange seamlessly. We expect the convergence on standards will be accomplished through SDOs.

In response to the XDM comment, we had paired the “XDR/XDM for Direct” with SOAP to enable the testing of SOAP with XDR using XDM packaging. While the comments from the IIS community are beyond the scope of this proposal, we note for clarity that consistent with the approach under the EHR Incentive Programs Stage 2 final rule (77 FR 53979), in the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this edition of the **Federal Register**, CMS adopts flexibility with respect to the public health and clinical data registry reporting objectives at § 495.316(d)(2)(iii). This policy allows states to specify the means of transmission of public health data, and otherwise change the public health agency reporting objective, so long as the state does not require functionality greater than what is required under the Medicare EHR Incentive Program CEHRT definition and the 2015 Edition certification criteria adopted in this final rule.

• *Healthcare Provider Directory—Query Request*

We proposed a new 2015 Edition “healthcare provider directory—query request” certification criterion that would require a Health IT Module to be capable of querying a directory using the Integrating the Healthcare Enterprise (IHE)¹⁴⁶ Healthcare Provider Directory (HPD).¹⁴⁷ In addition, we proposed including an optional capability within this certification criterion that addresses federated requirements. This optional capability would require a Health IT Module to follow the approved federation option of IHE HPD¹⁴⁸ to accomplish querying in federated environments. The proposed certification criterion sought to establish a minimum set of queries that a Health IT Module could support. We specified that the capabilities required by a Health IT Module would include: (1) Querying for an individual provider; (2) querying for an organizational provider; (3) querying for both individual and organizational provider in a single query; (4) querying for relationships between individual and organizational providers; and (5) electronically

processing responses according to the IHE HPD Profile.

Comments. Many commenters confirmed the value of provider directories and the ability for EHRs to query a provider directory. Most commenters stated that the proposed IHE HPD standard was immature and had few current implementations beyond pilot projects, with some commenters expressing concern about the costs associated with potential changes as the standard matures. Other commenters expressed concern with potential performance issues related to federated queries as well as the potential to proliferate redundant data. Commenters also noted, to ensure quality data, there needs to be: Centralized directories; a governance model for a centralized approach; and uniform directory sharing strategies among providers, organizations, and intermediaries. A commenter recommended the S&I Framework revisit consider expanding the scope of the use cases for provider directories and any solutions beyond query and response to include the maintenance of provider directories.

Some commenters stated a preference for an approach that utilized a RESTful architecture, such as FHIR, noting that a service stack utilizing SOAP protocols (as used by the IHE HPD protocol) is more difficult to implement and maintain.

Response. We thank commenters for their feedback and appreciate their comments in supporting the use of provider directories. We have not adopted this criterion as part of the 2015 Edition at this time. As noted in the draft ONC 2015 Interoperability Standards Advisory (draft ISA), the IHE HPD Profile is a provider directory standard and was listed as the best available standard in the draft ISA.¹⁴⁹ However, we agree with commenters that the IHE HPD standard requires further implementation to ensure stability and support widespread adoption and the same is true for the federated concepts. We also agree with commenters that RESTful solutions are being defined and may be a viable alternative in the near future. We note that HHS remains committed to advancing policies related to provider directories as a means of furthering health information exchange and interoperability. We believe that continued work in this space can inform the development and implementation of provider directory standards for consideration in future rulemaking.

• *Healthcare Provider Directory—Query Response*

We proposed to adopt a new certification criterion that would focus on the “query response” and include the corresponding set of capabilities to respond to a provider directory query. This proposed criterion was intended to complement the certification criterion we proposed for adoption related to health IT issuing a healthcare provider directory “query request,” and we explained that the proposed separation would provide developers with the flexibility to test and certify for provider directory “query” independent of the provider directory “response.” We stated that a health IT system would be able to be presented for testing and certification to both proposed certification criteria if applicable or just to one or the other as appropriate based on the product’s capabilities.

We proposed that directory sources must demonstrate the capability to respond to provider directory queries according to the IHE HPD profile and must respond to the following provider directory queries: Query for an individual provider; query for an organizational provider; and query for relationships between individual providers and organizational providers.

In addition we proposed including an optional capability within this certification criterion to address federated requirements that would require a Health IT Module to follow the approved federation option of for IHE HPD to accomplish querying in federated environments. The federation change proposal was approved in September, 2014 and was incorporated into the IHE HPD Profile.

Comments. Commenters submitted the same or equivalent comments as those submitted on the proposed “healthcare provider directory—query request” certification criterion, which are described above.

Response. We have not adopted this criterion for reasons specified in our response above for the proposed healthcare provider directory—query request” certification criterion.

• *Electronic Submission of Medical Documentation*

We proposed to adopt a new 2015 Edition “electronic submission of medical documentation” (esMD) certification criterion that focused on the electronic submission of medical documentation through four specific capabilities.

We proposed Capability 1 would require a Health IT Module be able to support the creation of a document in accordance with the HL7 Implementation Guide for CDA Release

¹⁴⁶ http://wiki.ihe.net/index.php?title=Healthcare_Provider_Directory.

¹⁴⁷ http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPDPdr.

¹⁴⁸ http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPDPdf.

¹⁴⁹ <http://www.healthit.gov/standards-advisory>.

2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1, Release 1—US Realm in combination with the C—CDA Release 2.0 standard. We proposed to adopt the most recent version of the CDP1 IG, which is designed to be used in conjunction with C—CDA Release 2.0 templates and makes it possible for providers to exchange a more comprehensive set of clinical information. We explained that a Health IT Module must be able to create a document that conforms to the CDP1 IG's requirements along with appropriate use of nullFlavors to indicate when information is not available in the medical record for section or entry level template required in the CDP1 IG. In addition, we proposed that a conformant Health IT Module must also demonstrate the ability to generate the document level templates as defined in the C—CDA Release 2.0, including the unstructured document. We proposed a list of the applicable document templates within the C—CDA Release 2.0 and CDP1 IG that would need to be tested and certified for specific settings for which a Health IT Module is designed: (regardless of setting) Diagnostic Imaging Report; Unstructured Document; Enhanced Operative Note Document; Enhanced Procedure Note Document; Interval Document; (ambulatory setting only) Enhanced Encounter Document; and (inpatient setting only) Enhanced Hospitalization Document.

We proposed Capability 2 would require a Health IT Module be able to support the use of digital signatures embedded in C—CDA Release 2.0 and CDP1 IG documents templates by adopting the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (DSDR IG).¹⁵⁰ This DSDR IG defines a method to embed digital signatures in a CDA document and provides an optional method to specify delegation of right assertions that may be included with the digital signatures. We proposed that for the purposes of certification, the optional method must be demonstrated to meet this certification criterion. The Proposed Rule listed the requirements that a system used to digitally sign C—CDA Release 2.0 or CDP1 IG documents must meet to create a valid digital signature that meets Federal Information Processing Standards (FIPS),¹⁵¹ Federal Information Security Management Act

of 2002 (FISMA),¹⁵² and Federal Bridge Certification Authority (FBCA) requirements.¹⁵³ For the purposes of testing and certification, we proposed that cryptographic module requirements must be met through compliance documentation, and the remaining capabilities listed in the Proposed Rule would be met through testing and certification assessment. We also proposed that a Health IT Module must demonstrate the ability to validate a digital signature embedded in a C—CDA Release 2.0 document that was conformant with the DSDR IG. The requirements proposed to perform this action are included in the DSDR IG.

We proposed Capability 3 would require a Health IT Module be able to support the creation and transmission of “external digital signatures” for documents that may be used to sign any document for the purpose of both data integrity and non-repudiation. The esMD Initiative defines the requirements in the Author of Record Level 1: Implementation Guide;¹⁵⁴ and we proposed to adopt the IG. We explained that this “signing” capability is intended for use when the sender of one or more documents needs to ensure that the transmitted documents include the non-repudiation identity of the sender and ensure that the recipient can validate that the documents have not been altered from the time of signing, and it is not intended to replace the ability to embed multiple digital signatures in a C—CDA Release 2.0 and CDP1 IG document.

We proposed Capability 4 would require a Health IT Module to support the creation and transmission of digital signatures for electronic transactions for the purpose of both data integrity and non-repudiation authenticity. The esMD Initiative defines the requirements in the Provider Profiles Authentication: Registration Implementation Guide;¹⁵⁵ and we proposed to adopt the IG. We explained that this “signing” capability is intended for use when the sender or recipient of a transaction needs to ensure that the transmitted information include the non-repudiation identity of

the sender and ensure that the recipient can validate that the authenticity and integrity of the transaction information, and it is not intended to replace the digital signature requirements defined in either Capability 2 or 3 above.

Comments. A few commenters expressed support for this criterion. However, many more commenters expressed concerns. Commenters stated that the IG was immature, there had been few pilots, and it was not proposed as required for Stage 3 of the EHR Incentive Programs. A few commenters also expressed concern about advancing a digital signature standard that may conflict with the existing Drug Enforcement Administration (DEA) standard for electronic prescribing of controlled substances. Other commenters expressed concerns that the changes to existing administrative and clinical workflows would be required to integrate esMD at a significant cost and resource burden.

Response. We have not adopted this criterion as part of the 2015 Edition at this time. We acknowledge and agree with commenters' stated concerns about the relative immaturity of the proposed standards and recommendations for further industry piloting and implementation to determine the usefulness of the standards for meeting the stated use cases. We will continue to monitor the development and implementation of esMD and will consider whether proposing a certification criterion or criteria to support esMD is appropriate for a future rulemaking.

- *Work Information—Industry/ Occupation (I/O) Data—Request for Comment*

In the Proposed Rule, we requested that commenters consider what additional support might be needed for health IT developers, implementers, and users to effectively include a certification criterion that would require health IT to enable a user to record, change, and access (all electronically) the following data elements in structured format:

- Patients' employment status and primary activities (e.g., volunteer work);
- Patients' current I/O, linked to one another and with time-stamp, including start date;
- Patients' usual I/O, linked to one another and with time-stamp, including start year and duration in years; and
- Patients' history of occupation with a time and date stamp for when the history was collected (to note, this is focused on the capability to record a history, not a requirement that a history must be recorded or that a patient

¹⁵² <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>.

¹⁵³ <http://www.idmanagement.gov/sites/default/files/documents/FBCA%20Certificate%20Policy%20v2.27.pdf>.

¹⁵⁴ <http://wiki.siframework.org/file/view/esMD%20AoR%20Level%201%20Implementation%20Guide%20v5%20FINAL.docx/539084894/esMD%20AoR%20Level%201%20Implementation%20Guide%20v5%20FINAL.docx>.

¹⁵⁵ <http://wiki.siframework.org/file/view/esMD%20Use%20Case%201%20Implementation%20Guide%20v24%20FINAL.docx/539084920/esMD%20Use%20Case%201%20Implementation%20Guide%20V24%20FINAL.docx>.

¹⁵⁰ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=375.

¹⁵¹ <http://www.nist.gov/itl/fips.cfm>.

history be recorded for a certain historical period of time).

We also solicited public comment on the experience health IT developers and health care providers have had in recording, coding, and using I/O data, which included any innovation that is making I/O data more useful for providers.

To better understand the health care needs associated with work data, we specifically solicited public comment from *health care providers, provider organizations, and patients* on the following:

- The usefulness for providers to be able to access current and usual I/O and related data in the EHR, including whether additional data elements, such as work schedule, are useful.

- The usefulness of a history of positions provided as current I/O, with data from each position time-stamped, linked, retained, and accessible as part of the longitudinal patient care (medical) record.

- Narrative text (vs. codes) for both current and usual I/O.

- CDC Census codes for both current and usual I/O; available through PHIN VADS at <https://phinvads.cdc.gov/vads/SearchVocab.action>.

- SNOMED CT® codes for occupation (current codes or potentially developed codes).

- Other standards and codes that may be in use by the health IT industry for both current and usual I/O.

Comments. Many commenters supported the capture of structured industry/occupation (I/O) data in EHRs and other health IT systems to improve patient health outcomes for health issues wholly or partially caused by work and for health conditions whose management is affected by work. These commenters stated that the structured capture of I/O information would also improve interoperability as the information being collected today is largely unstructured. Commenters did, however, express a number of concerns relating to maturity of available standards for representing the information and the time needed for a provider to collect structured I/O information. In regard to standards, a number of commenters suggested that the codes currently available in SNOMED CT® are not specific enough to capture the level of I/O detail that would be of clinical value. Instead, commenters stated that the industry is working through a NIOSH-led effort to develop an interface between health IT and an I/O coding knowledge engine that would guide users through choosing CDC Census I/O titles based on the North American Industry Coding

System (NAICS) and the Bureau of Labor Statistics Standard Occupational Codes (SOC). Commenters mentioned that this work is still underway and suggested we wait until this standard is available for use before adopting requirements for capture of I/O information through certification. Commenters stated that the NAICS/SOC code set is considered the most authoritative and mature code set. These comments further stated that the adoption of SNOMED CT® would not align with the NAICS/SOC code set or the NIOSH tool and, therefore, could potentially create unnecessary burden.

Response. We thank commenters for the thoughtful feedback. As stated in the 2015 Edition proposed rule (80 FR 16829), we continue to believe in the value of I/O information to provide opportunities for health care providers to improve patient health outcomes for health issues wholly or partially caused by work and for health conditions whose management is affected by work. Our long-term goal is for health care providers to use 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 information needs of groups of patients.

Given the feedback about the immaturity of the standards currently available for supporting these goals, we have not adopted a 2015 Edition certification criterion for the collection of I/O information. We are, however, optimistic about the NIOSH-led effort to develop a tool based on the NAICS/SOC code set and believe that it can provide a much-needed authoritative standard that can enable the detailed recording of I/O titles. We intend to monitor the development of such a tool and will consider it and the additional comments we received regarding structured capture of I/O information for future rulemaking.

- *U.S. Uniformed/Military Service Data—Request for Comment*

To improve coding of military and all uniformed history, we stated in the Proposed Rule that a promising path forward would be to add codes to the U.S. Extension of SNOMED-CT®. Therefore, we requested comment on the following:

- Whether a potential certification criterion should be focused solely on U.S. military service or all uniformed service members (e.g., commissioned officers of the USPHS and NOAA);

- Whether the U.S. Extension of SNOMED-CT® is the most appropriate vocabulary code set or whether other

vocabulary code sets may be appropriate; and

- The concepts/values we should use to capture U.S. military service or all uniformed service status. We ask commenters to consider the work of NIOSH on I/O information as it relates to capturing military service.

Comments. A large number of commenters suggested that we adopt certification to capture military service. Commenters stated that capturing information on military service could identify significant occupational exposure risks unique to military service, including overseas deployment and combat environments. Commenters stated that capturing a patient's military service could also ensure that a patient receives all the applicable health care benefits (e.g., military and veteran's benefits), s/he is entitled to by alerting medical professionals to the patient's service history. Commenters stated that capturing military service information could also enable the assembly of a complete longitudinal record of care for a U.S. service member, including merging of health care data from different sources.

Some commenters supported and opposed the collection of non-military service uniformed service status (e.g., service data for U.S. Public Health Service and National Oceanic and Atmospheric Administration uniformed officers) as part of military/uniformed service data or collected separately.

In regard to vocabulary standards for collecting military service information, commenters submitted mixed comments on whether SNOMED CT® codes were sufficiently detailed and captured the right types of military service information. Commenters pointed out that SNOMED CT® contains some concepts to capture high-level military history, including current or past active military service and combat zone service. However, other commenters expressed concern that current SNOMED CT® codes for military history are not detailed enough to be of clinical value. As an example, commenters noted that while SNOMED CT® can document general information about whether the person served in the military, it does not allow for the capture of the individual's specific occupation.

Commenters stated that the NIOSH work on developing a tool for industry and occupation codes as described in the "Work Information—Industry/Occupation Data—Request for Comment" section above would include detailed codes for military service branch; service status; commissioned, warrant officer, non-commissioned and

enlisted service; and many occupational areas. Commenters noted, however, that the NIOSH tool is not expected to be able to capture Military Occupational Specialty (MOS) codes maintained by the Armed Forces or areas of service (such as ships, stations, and combat theaters).

Response. We thank commenters for the thoughtful feedback. As stated in the 2015 Edition proposed rule (80 FR 16830), we continue to believe in the value of capturing patient military service and other uniformed service information. We believe recording U.S. uniformed/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 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.

Our long-term goal is for health care providers to use military service information to provide better care for our nation's veterans. However, given the feedback about SNOMED CT and the NIOSH tool under development, we have not adopted a 2015 Edition certification criterion for military service. We plan to continue to work with the appropriate stakeholders to develop the appropriate values and code sets that would enable consideration of a relevant certification criterion in a future rulemaking.

• *Pharmacogenomics Request for Comment*

Pharmacogenomics data identifies genetic variants in individuals that alter their metabolism or other interactions with medications and can lead to serious adverse events. This information is being included in an increasing number of FDA-approved drug labels. Health IT that can capture pharmacogenomics information could be used to improve patient safety and enhance patient outcomes. In the Proposed Rule, we stated that to our knowledge, in general, health IT has not yet captured genomic and genetic patient information—the presence of clinically significant genomic variants—in a structured manner such as exists for

other categorical clinical findings or laboratory-derived data.¹⁵⁶

In collaboration with the National Institutes of Health, we solicited comment on whether:

- The 2015 Edition “medication allergy list” certification criterion should include the capability to integrate genotype-based drug metabolizer rate information;
- the 2015 Edition “drug-drug, drug-allergy interactions checks for CPOE” certification criterion or as a separate certification criterion should include pharmacogenomic CDS for “drug-genome interactions;”
- we should offer 2015 Edition certification for CDS that incorporate a patient's pharmacogenomic genotype data into the CPOE prescribing process with the goal of avoiding adverse prescribing outcomes for known drug-genotype interactions;
- there are certification approaches that could enhance the end-user's (provider's) adoption and continued use of health IT implementations that guide prescribing through CDS using pharmacogenomic data; and
- there are existing or developing standards applicable to the capture, storage, display, and exchange of potentially clinically relevant genomic data, including the pharmacogenomic subset.

Comments. Most commenters agreed on the value of pharmacogenomics data as an integral part of medicine in the future, but indicated that the standards were currently not mature enough to support this functionality and that it was premature to attempt to include it in certification. Commenters noted that the inclusion of pharmacogenomics data can link variants to changes in drug metabolism or response, especially when clinical guidelines exist about dosing for variant carriers and how it can enable pharmacogenomic-based therapeutic recommendations integrated into computerized systems for drug prescription, automated medication surveillance, and EHRs.

In certain instances, commenters supported inclusion of the pharmacogenomic variant causing the allergy if such information is known for the patient. However, other commenters suggested that studies are needed to prove effectiveness and support inclusion of such data. Some commenters cited drug-drug and drug-allergy interaction alerts without an appropriate filter as the largest source of alert fatigue in relation to the value.

¹⁵⁶ <http://www.genomebc.ca/education/articles/genomics-vs-genetics/>; and <http://www.who.int/genomics/geneticsVSgenomics/en/>.

Many other commenters also cited concerns over other CDS alert fatigue, poor return on investment, high costs of testing, and the staff resources needed to maintain the CDS in a rapidly evolving area with little evidence to show that it improves overall outcomes or reduces costs. A few commenters noted the existence of third-party web services that provide drug-genome interaction checking functionality that are easily integrated with EHRs.

Response. While we believe in the value of CDS including drug-drug/drug-allergy interaction checks for improving patient safety, we agree that standards are not mature to support incorporating pharmacogenomics data into health IT certification at this point in time. We encourage the industry to continue its work on developing standards for incorporating this information into health IT. We note that we view the use of pharmacogenomics data in health IT as one of the early tangible products of the Precision Medicine Initiative,¹⁵⁷ and intend to monitor and consider developments in this field for future rulemaking.

Privacy and Security Considerations for Pharmacogenomics

We solicited comment on whether:

- We should offer certification for health IT functionality that could facilitate HIPAA-compliant sharing of discrete elements of a patient's genomic information from their record to the family history section of a relative's record;
- the proposed “data segmentation for privacy” criteria would provide needed health IT functions with respect to the storage, use, transmission, and disclosure of genetic, genomic, and pharmacogenomics information that is subject to protections under HIPAA and additional state and federal privacy and protection laws such as the Genetic Information Nondiscrimination Act (GINA);¹⁵⁸
- the proposed “data segmentation for privacy” criteria adequately balance complex genetic privacy issues, such as those related to behavioral health, with the clinical value of context-appropriate availability of a patient's actionable genetic and genomic information;
- health IT should be required to apply different rules for the use and exchange of genetic, genome, and pharmacogenomics data based on different groupings of diseases or conditions based on the sensitivity of

¹⁵⁷ <http://www.nih.gov/precisionmedicine/>.

¹⁵⁸ <http://ghr.nlm.nih.gov/spotlight=thegeneticinformationnondiscriminationatina>.

the information, such as those related to behavioral health; and

- there are other factors we should consider for health IT that allows the user to use or disclose genetic information in a manner compliant with federal and state privacy laws.

Comments. Many commenters noted privacy concerns stating it is essential to understand and implement proper privacy and security requirements associated with certified functionalities. Commenters indicated certified functionalities must not lead to discrimination against individuals or their families who may be at risk of developing future health issues. These commenters were concerned that there is not sufficient technical maturity to support privacy protections for genetic data, segmented to the genetic data atom. In particular, commenters were concerned about behavioral health implications, the risk of revealing latent conditions and providing information on close relatives, and the effect on insurance coverage. In addition to privacy concerns, select comments noted ethical and legal implications of any gene-related functionality. Some commenters suggested that the features of the “data segmentation for privacy” criteria should be incorporated into any inclusion of pharmacogenomic data.

Response. We thank commenters for sharing their concerns and feedback. As noted above, standards are not mature to support incorporating pharmacogenomics data into health IT certification at this point in time. We will continue to consider privacy and security implications and stakeholder concerns as they relate to any potential future rulemaking for pharmacogenomics data. To note, we have adopted the proposed “data segmentation for privacy” criteria (see section III.3 of this preamble) and will further assess and consider its value in the segmentation of individually identifiable genetic information that is protected by federal and state privacy laws as part of any future rulemaking related to pharmacogenomics data.

B. Definitions

1. Base EHR Definitions

We proposed to adopt a Base EHR definition specific to the 2015 Edition (*i.e.*, a 2015 Edition Base EHR definition) at § 170.102 and rename the current Base EHR definition at § 170.102 as the 2014 Edition Base EHR definition. We proposed a 2015 Edition Base EHR definition that would differ from the 2014 Edition Base EHR definition in the following ways:

- It would not include privacy and security capabilities and certification criteria.
- It would only include capabilities to record and export CQM data (§ 170.315(c)(1)) and not the other CQM capabilities such as import, calculate, and “report to CMS.”
- It would include the 2015 Edition “smoking status” certification criterion as patient demographic and clinical health information data consistent with statutory requirements.¹⁵⁹
- It would include the 2015 Edition “implantable device list” certification criterion as patient demographic and clinical health information data consistent with statutory requirements.¹⁶⁰
- It would include the 2015 Edition “application access to Common Clinical Data Set” certification criterion as a capability to both capture and query information relevant to health care quality and exchange electronic health information with, and integrate such information from other sources.¹⁶¹
- It would include the proposed 2015 Edition certification criteria that correspond to the remaining 2014 Edition certification criteria referenced in the “2014 Edition” Base EHR definition (*i.e.*, CPOE, demographics, problem list, medication list, medication allergy list, CDS, transitions of care, data portability, and relevant transport certification criteria). On the inclusion of transport certification criteria, we proposed to include the “Direct Project” criterion (§ 170.315(h)(1)) as well as the “Direct Project, Edge Protocol and XDR/XDM” criterion (§ 170.315(h)(2)) as equivalent alternative means for meeting the 2015 Edition Base EHR definition.

Comments. A commenter recommended removing the Base EHR definition from the 2015 Edition rulemaking and including it in the EHR Incentive Programs rulemaking. Several commenters suggested that we modify the Base EHR definition to accommodate use of health IT that is certified to the 2014 Edition and the 2015 Edition, stating that this will give providers flexibility as they upgrade to 2015 Edition and begin to achieve Stage 3.

¹⁵⁹ A Base EHR is the regulatory term we have given to what the HITECH Act defines as a “qualified EHR.” Our Base EHR definition(s) include all capabilities found in the “qualified EHR.” Please see the 2014 Edition final rule (77 FR 54262) for further explanation.

¹⁶⁰ A capability included in the Base EHR definition, which originates from the “qualified EHR” definition found in the HITECH Act.

¹⁶¹ These are capabilities included in the Base EHR definition, which originate from the “qualified EHR” definition found in the HITECH Act.

Commenters provided varying recommendations for the criteria that should be included in the Base EHR definition. Some commenters stated that separating privacy and security certification criteria from the Base EHR definition is overly burdensome or confusing, or may create security gaps. A commenter recommended that the “data export” and “application access to Common Clinical Data Set” criteria are more appropriate as “modular” certification, rather than as part of the Base EHR definition. A commenter suggested that “drug-drug, drug-allergy interaction checks for CPOE” criterion be included in the Base EHR definition as it is specifically for CPOE, which is part of the Base EHR definition. Some commenters rejected the idea of including the “implantable device list” criterion in the Base EHR definition, while other commenters supported inclusion of this criterion and noted that this capability would improve care coordination. A few commenters voiced support for the inclusion of the Direct Edge Protocol as an alternative to Direct Project. Some commenters recommended that sexual orientation and gender identity data be included in the Base EHR definition.

Response. We have renamed the current Base EHR definition at § 170.102 as the 2014 Edition Base EHR definition and adopted the 2015 Base EHR definition largely as proposed. In Table 7 below, we list the 2015 Edition certification criteria included in the 2015 Edition Base EHR definition. Many of the proposed criteria have been revised in response to comments and we refer readers to section III.A.1 of this preamble for a detailed discussion of those criteria and revisions.

Since the establishment of the 2014 Edition Base EHR definition (77 FR 54263–64), we have tried to limit the criteria included in the Base EHR definition to those necessary to meet the HITECH Act requirements and our policy goals. In this regard, we have not included “drug-drug, drug-allergy interaction checks for CPOE” criterion in the 2015 Edition Base EHR definition just as we did not for the 2014 Edition Base EHR definition (see 77 FR 54264). We have, however, included the “implantable device list” criterion in this 2015 Edition Base EHR definition for the reasons stated in the Proposed Rule (80 FR 16825) and discussed under the “implantable device list” criterion in section III.A.1 of this preamble. We have also included the Direct transport alternatives for the reasons discussed in the Proposed Rule (80 FR 16862) and under “transport methods and other protocols” in section III.A.1 of this

preamble. In response to comments and other considerations, the “demographics” certification criterion (§ 170.315(a)(5)) now includes sexual orientation and gender identity as data elements, thus including this data in the 2015 Edition Base EHR definition. We discuss this further under the “demographics” certification criterion in section III.A.1 of this preamble. We also note that given our decision to split the “application access to Common Clinical Data Set” criterion into three separate criteria, we have accordingly modified the 2015 Edition Base EHR definition to include these three criteria.

In regard to the lack of inclusion of privacy and security criteria in the 2015 Edition Base EHR definition, we believe commenters are confused by our approach. As discussed in more detail under the “privacy and security” heading in section IV.C.1 of this preamble, Health IT Modules presented for certification to criteria listed in the 2015 Base EHR definition and other 2015 Edition certification criteria *will be* subject to the applicable privacy and security criteria for the purposes of certification. Our new privacy and security certification approach places responsibility more clearly on the health IT developer presenting its product for

certification to ensure that its health IT has the applicable privacy and security capabilities in order to be certified. This is counter to the approach under the 2014 Edition Base EHR definition, which puts the onus on the provider to ensure he/she has health IT certified to the privacy and security criteria included in the Base EHR definition.

The CQM capabilities noted above as not included in the 2015 Edition Base EHR definition have, however, been included the Certified EHR Technology (CEHRT) definition under the EHR Incentive Programs. We refer readers to the next section (“2. Certified EHR Technology Definition”) and Table 4 found in section III.A.3 (“2015 Edition Health IT Certification Criteria Associated with the EHR Incentive Programs Stage 3”) of this preamble for further information and guidance on the relationship of the 2015 Edition Base EHR definition and the 2015 Edition certification criteria with the CEHRT definition. We also refer readers to the CEHRT definition finalized in the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register** as the authoritative source for the requirements to meet the CEHRT definition.

We seek to clarify the 2015 Base EHR definition in response to comments. First, the Base EHR definition is just a definition not a single certified product. As noted in 2014 Edition final rule (77 FR 54263), the Base EHR definition may be met using multiple Health IT Modules. Therefore, to the commenter’s point, Health IT Modules separately certified to the “data export,” “application access” criteria, and other criteria included in the 2015 Edition Base EHR definition can be combined to meet the definition. Second, we believe the defining of the Base EHR definition should remain in the rulemaking as the Base EHR definition is only one part of the CEHRT definition and may serve other purposes beyond its inclusion in the CEHRT definition and supporting the EHR Incentive Programs. Third, with the 2014 and 2015 Base EHR definitions’ inclusion in the CEHRT definition and the CEHRT definition’s included flexibility to use both health IT certified to the 2014 and 2015 Editions for the specified EHR reporting periods, we do not believe there would be a benefit to developing a single Base EHR definition that referenced both the 2014 and 2015 Editions. Rather, we believe this would cause confusion, particularly in relationship to the CEHRT definition.

TABLE 7—CERTIFICATION CRITERIA REQUIRED TO SATISFY THE 2015 EDITION BASE EHR DEFINITION

Base EHR capabilities	Certification criteria
<i>Includes patient demographic and clinical health information, such as medical history and problem lists.</i>	Demographics § 170.315(a)(5). Problem List § 170.315(a)(6). Medication List § 170.315(a)(7). Medication Allergy List § 170.315(a)(8). Smoking Status § 170.315(a)(11). Implantable Device List § 170.315(a)(14).
<i>Capacity to provide clinical decision support</i>	Clinical Decision Support § 170.315(a)(9).
<i>Capacity to support physician order entry</i>	Computerized Provider Order Entry § 170.315(a)(1), (2) or (3).
<i>Capacity to capture and query information relevant to health care quality</i>	Clinical Quality Measures—Record and Export § 170.315(c)(1).
<i>Capacity to exchange electronic health information with, and integrate such information from other sources.</i>	Transitions of Care § 170.315(b)(1). Data Export § 170.315(b)(6). Application Access—Patient Selection § 170.315(g)(7). Application Access—Data Category Request § 170.315(g)(8). Application Access—All Data Request § 170.315(g)(9). Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2).

Marketing

In the Proposed Rule, we noted that we would continue the same marketing policy that we adopted for the 2014 Edition as it relates to the 2015 Edition Base EHR definition (*i.e.*, health IT developers would have the ability to market their technology as meeting the 2015 Edition Base EHR definition when their Health IT Module(s) is/are certified to all the 2015 Edition certification criteria included in the 2015 Edition

Base EHR definition) (see also 77 FR 54273).

Comments. A commenter requested clarification regarding how we anticipate ONC–ACBs will monitor the use of the term “Base EHR definition.”

Response. We will maintain this policy with the 2015 Edition. We anticipate that ONC–ACBs will continue to monitor health IT developers and their certified health IT as they do now with regard to the 2014 Edition Base EHR definition. ONC–ACBs have various oversight responsibilities for

certified health IT, including ensuring the public disclosure of certain information for certified health IT (see § 170.523(k)); the proper use of the Certified HIT certification mark (see § 170.523(l)); and responsibilities under ISO/IEC 17065 (2012) (ISO 17065),¹⁶² to which they are accredited. In regard to ISO 17065, section 4.1.3.2 states “incorrect references to the certification scheme or misleading use of licenses,

¹⁶² This standard is incorporated by reference in 45 CFR 170.599.

certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.” Consistent with the performance of these responsibilities, we anticipate ONC-ACBs will be able to identify any improper marketing association of certified health IT with the “Base EHR definition.” We also note that any purchaser or other stakeholder may inform us of any alleged improper marketing association of certified health IT with the “Base EHR definition.”

2. Certified EHR Technology Definition

We proposed to remove the Certified EHR Technology (CEHRT) definition from § 170.102, effective with this final rule. We explained that the CEHRT definition has always been defined in a manner that supports the EHR Incentive Programs and would more appropriately reside solely within the EHR Incentive Programs regulations to be consistent with our approach in this final rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. We noted that this removal of the definition should add administrative simplicity in that regulatory provisions, which EHR Incentive Programs participants must meet (e.g., the CEHRT definition), would be defined within the context of rulemakings for those programs. We further noted that, as proposed in the EHR Incentive Programs Stage 3 proposed rule (80 FR 16767), CMS would adopt a CEHRT definition in 42 CFR 495.4 that would cover all relevant compliance timelines (i.e., specify the CEHRT definition applicable for each year/EHR reporting period) and EHR Incentive Programs requirements. We explained that the CEHRT definition proposed by CMS would also continue to point to the relevant Base EHR definitions¹⁶³ adopted or proposed by ONC and to other ONC-adopted and proposed certification criteria relevant to the EHR Incentive Programs.

Comments. The overwhelming majority of commenters were supportive of moving the CEHRT definition into the EHR Incentive Programs. One commenter requested that we and CMS identify which certification criteria are required for to meet the CEHRT definition and be a meaningful user.

¹⁶³ This is required by the HITECH Act under the term “Qualified EHR” and references a foundational set of certified capabilities all EPs, eligible hospitals, and CAHs need to adopt.

Many commenters suggested that the CEHRT definition should accommodate use of health IT certified to the 2014 Edition and health IT certified to the 2015 Edition as this approach would give providers flexibility as they upgrade to 2015 Edition. Many commenters also requested that we work closely with CMS and other organizations to align any changes to the CEHRT definition or adoption of proposed criteria for inclusion in programs beyond the EHR Incentive Programs.

Response. We have finalized our proposal to remove the CEHRT definition for 2015 certification. As proposed in the EHR Incentive Programs Stage 3 proposed rule, a combination of health IT certified to the 2014 Edition and 2015 Edition may be used during EHR reporting periods through calendar year 2017. Table 4 found in section III.A.3 (“2015 Edition Health IT Certification Criteria Associated with the EHR Incentive Programs Stage 3”) provides guidance on the relationship of the 2015 Edition certification criteria with the CEHRT definition and Stage 3 of the EHR Incentive Programs. We also refer readers to the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register** as the authoritative source for the requirements to meet the CEHRT definition (and meaningful use objectives and measures). We note that supplemental guidance documents we intend to issue with this final rule will also identify the 2015 Edition certification criteria necessary to meet the CEHRT definition and are associated with meaningful use objectives and measures. We further note that we intend to work closely with CMS and other stakeholders to ensure alignment of the 2015 Edition and CEHRT definition to support settings, use cases, and programs beyond the EHR Incentive Programs.

3. Common Clinical Data Set Definition

We received general comments on our overall proposal and comments on the data and vocabulary standards included in the proposed definition. We have divided and responded to the comments in a similar manner.

Name Change

We proposed to revise the “Common MU Data Set” definition in § 170.102 and change the name to “Common Clinical Data Set,” which aligned with our proposed approach to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and

for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. We explained the procedural requirement to remove the previous name from the CFR and add the new name. We also proposed to change references to the “Common MU Data Set” in the 2014 Edition (§ 170.314) to “Common Clinical Data Set.”

Comments. The majority of commenters expressed support for the name change. One commenter did not support the name change stating it would add confusion and lack of continuity. One commenter stated the term “clinical” may be too restrictive.

Response. We thank commenters for the support for the name change and have finalized this proposal and related changes to the CFR. The term “Common Clinical Data Set” aligns with our approach to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. We believe “clinical” is a suitable descriptor for the purpose and context within which the Common Clinical Data Set has been defined (i.e., for the certification of health IT under the ONC Health IT Certification Program).

We refer readers to Table 8 below for a complete listing of the data included in the Common Clinical Data Set and the associated standards.

Vocabulary Standards

We proposed to revise the definition to include new and updated standards and code sets (HL7 Version 3 for sex; “Race & Ethnicity—CDC” code system in PHIN VADS and the OMB standard for race and ethnicity; RFC 5646 for preferred language, the September 2014 Release of the U.S. Edition of SNOMED CT® for problems and procedures; the February 2, 2015 monthly version of RxNorm for medications and medication allergies; and LOINC® version 2.50 for laboratory tests). We noted that for race and ethnicity a Health IT Module must be able to express both detailed races and ethnicities according to the “Race & Ethnicity—CDC” code system and the aggregate OMB code for each race and ethnicity identified by the patient.

We emphasized that the proposed revisions would *not* change the standards, codes sets, and data requirements specified in the Common Clinical Data Set for 2014 Edition certification and would only apply to a Health IT Module certified to the 2015

Edition certification criteria that reference the Common Clinical Data Set.

Comments. The majority of commenters expressed support updating the definition to reflect new and updated standards and code sets. Some commenters stated that specific versions of vocabulary standards may become obsolete or superseded and systems should be permitted to use later versions.

Response. We thank commenters for their support. We have adopted the proposed data elements and referenced standards for the Common Clinical Data Set definition. We note that we have adopted newer versions of SNOMED CT®, RxNorm, and LOINC® than we proposed as the baseline versions for certification. We have also more specifically identified the CDC Race and Ethnicity code set (CDC Race and Ethnicity Code Set Version 1.0 (March 2000)) as compared to the identification in the Proposed Rule. We note this code set remains part of the PHIN Vocabulary Access and Distribution System (VADS) Release 3.3.9. We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for further discussion of our adoption of minimum standards code sets and our decision to adopt these newer versions. We also remind readers that health IT developers may seek certification to newer versions than the adopted baseline versions of minimum standards code sets, unless the Secretary specifically prohibits it.

Comments. One commenter requested clarification regarding which codes for race and ethnicities are included in the Common Clinical Data Set.

Response. Both the CDC Race and Ethnicity code set in PHIN VADS and the OMB standard for race and ethnicity are included for certification to the 2015 Edition, but only the OMB standard for certification to the 2014 Edition.

Comments. One commenter requested clarification if the C–CDA Release 1.1 will be applicable for certification to the “Common MU Data Set” or the Common Clinical Data Set.

Response. For the 2014 Edition certification criteria that reference the Common Clinical Data Set (formerly the “Common MU Data Set”), the C–CDA Release 1.1 is the referenced standard.

Immunizations

We proposed to include immunizations in the Common Clinical Data Set for 2015 Edition certification. We noted that the C–CDA Release 2.0 could support NDC codes as a translational data element, but the CVX code is required to accompany it. We stated that it would not be a heavy burden to map from an NDC code to a

CVX code because a mapping from NDC codes to CVX codes is publicly available. Therefore, for the purposes of including immunizations in the Common Clinical Data Set for 2015 Edition certification, immunizations would be required to be coded according to the CVX code set (HL7 Standard Code Set CVX—Vaccines Administered, updates through February 2, 2015) and the NDC code set (NDC—Vaccine NDC Linker, updates through January 15, 2015).

Comments. Multiple commenters expressed concerns with mapping burden. One commenter stated that the inclusion of immunizations mapped to NDC codes may be problematic as most providers may not include NDC codes when documenting immunizations particularly for historical immunizations and immunizations received outside the practice setting. Some commenters commented that IIS transmission doesn’t seem to align since IIS transmission is based on HL7 V2 and not C–CDA R2.

Response. We have included immunizations in the definition according to the standards proposed. We note that we have adopted newer versions of NDC and CVX than we proposed as the baseline versions for certification. We refer readers to section III.A.2.c (“Minimum Standards” Code Sets) for further discussion of our adoption of minimum standards code sets and our decision to adopt these newer versions. We do not believe this creates an undue mapping burden as CDC provides a publicly available mapping of NDC codes for vaccines to CVX codes.¹⁶⁴ We also note that these requirements are to test and certify a Health IT Module’s capabilities; and they do not require a provider to send an immunization using a certain code. IIS transmission based on HL7 V2 serves a different use case than the Common Clinical Data Set and the C–CDA, which support transitions of care, data export, API access, and a patient’s ability to view, download, and transmit their health information.

Vital Signs

We proposed to include vital signs in the Common Clinical Data Set according to specific LOINC® codes, metadata, and relevant UCUM unit of measures. We also proposed to offer optional certification to pediatric vital signs as part of the Common Clinical Data Set.

We have not adopted the proposed vital signs criterion as discussed in section III.A.5 above.

Comments. Commenters generally supported the expanded list of proposed vital signs for the Common Clinical Data Set with concerns on a few items. For systolic and diastolic blood pressure, a few commenters did not support the separating out of these from blood pressure generally as their systems allow both to be collected in one field with a delineator (e.g., a comma or forwards-slash) that can be used to parse the two fields. A few commenters suggested that “body weight measured” specifies the method of measurement and noted that there are other ways that body weight is collected, such as self-reporting. There was a lot of concern over the choice of “oxygen saturation in arterial blood by pulse oximetry” and a few commenters suggested there are multiple ways of collecting pulse oximetry. Commenters noted that BMI is typically a calculated value from height and weight, and were concerned that users should not be allowed to manually enter in a BMI as it could be incorrectly calculated. Last, commenters were concerned that mean blood pressure is not a vital sign typically collected in all provider settings, and is more specific to surgery, ED, and ICU settings.

Response. We thank commenters for their feedback. While we have not adopted the proposed 2015 Edition “vital signs” criterion as discussed in section III.A.5 above, we have included vital signs in the Common Clinical Data Set for certification to the 2015 Edition consistent with the same vocabulary standards as specified by the C–CDA Release 2.1 standard (i.e., vital signs are exchanged using a LOINC® code, and with a Unified Code of Units of Measure (UCUM) code for the unit of measure associated with the vital sign measurement). We discuss the list of vital signs that must be exchanged in this manner below, including changes made in comparison to our proposals.

We continue to differentiate between systolic and diastolic blood pressure as two distinct vital signs, but note that Health IT Modules may store and display the two values in one field as long as they are exchanged as two separate fields. We have revised “body weight measured” to “body weight.” We have revised “oxygen saturation in arterial blood by pulse oximetry” to “pulse oximetry” and will allow implementers, for the purposes of testing and certification, to choose the LOINC® code with “pulse oximetry” in its name that best represents the method of measurement for exchange. We note that we believe that inhaled oxygen

¹⁶⁴ <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc>. See also: http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.

concentration is a necessary measurement in order to correctly interpret the pulse oximetry measurement, and are including it in the list of vital signs for exchange. This does not mean that providers are required to capture this measurement every time, only that certified Health IT Modules are able to exchange the value if present. Last, we have removed BMI and mean blood pressure from the list of vital signs.

In summary, we require that the following vital signs must be exchanged as part of the Common Clinical Data Set using a LOINC® code and with a UCUM code for the unit of measure associated with the vital sign measurement:

- Systolic blood pressure;
- Diastolic blood pressure;
- Body height;
- Body weight;
- Heart rate;
- Respiratory rate;
- Body temperature;
- Pulse oximetry; and
- Inhaled oxygen concentration.

We believe this list represents vital signs commonly collected across provider settings today and is a start at defining a minimum set of vital signs, but note that we will continue to work with stakeholders to determine and consider if this list should be revised through a future rulemaking.

Comments. A number of commenters were concerned that UCUM does not allow for mixing of units, and were therefore concerned that a height of 5 feet and 6 inches (5'6") could not be represented with an associated UCUM code for the unit of measure.

Response. We note that systems have the flexibility to choose how to display the vital sign measurement. Our requirement only specifies that the vital sign measurement must be exchanged using an applicable unit of measurement with a UCUM code. Therefore, systems could exchange a height of 5'6" as 66 inches or 5.5 feet or 167.64 centimeters using the appropriate UCUM code to represent the unit of measure for the measurement. Note that we provide this as an example only, and leave the decision on the appropriate unit of measure to the developers and providers. As noted in the 2015 Edition proposed rule (80 FR16818), LOINC provides a translation table¹⁶⁵ that enumerates UCUM syntax for a subset of UCUM codes that are commonly used in health IT that may be a useful reference for stakeholders. We would also suggest that health IT developers and providers follow the

guidance provided in C–CDA Release 2.1 for exchanging vital signs.

Comments. Commenters were generally supportive of the proposed optional pediatric vital signs.

Response. We have adopted the pediatric vital signs as proposed for inclusion in the Common Clinical Data Set definition as optional for exchange. We note that as discussed in the 2015 Edition proposed rule, CDC recommends the use of these pediatric vital signs for settings of care in which pediatric and adolescent patients are seen (80 FR 16818–16819) as part of best practices. The availability of a reference range/scale or growth curve can help with proper interpretation of the measurements for the BMI percentile per age and sex and weight for age per length and sex. Thus, we are including the reference range/scale or growth curve for each of these two pediatric vital signs as part of the Common Clinical Data Set definition for certification, and would suggest that providers include this information as appropriate. We note that the C–CDA Release 2.1 standard does allow for including additional clinically relevant information with vital signs.

Unique Device Identifier(s)

We proposed to include the Unique Device Identifier(s) of a patient's Implantable Device(s) for certification to the 2015 Edition.

Comments. Some commenters were in agreement with including UDIs, while other commenters suggested removing UDIs until more progress has been made with medical device identifier manufacturers and utilization among providers.

Response. We have included UDIs in the definition and require it be recorded in accordance with the "Product Instance" in the "Procedure Activity Procedure Section" of the C–CDA 2.1. This specificity within the C–CDA will make this information more easily retrievable. As discussed in more detail under the "implantable device list" certification criterion in section III.A.3 of this preamble, this information leads to improved patient safety when available to providers. By including this information in the Common Clinical Data Set, a Health IT Module certified to criteria referencing the Common Clinical Data Set would be capable of exchanging this information and further facilitating improvements in patient safety.

Assessment and Plan of Treatment, Goals, and Health Concerns

We proposed to include the "assessment and plan of treatment,"

"goals," and "health concerns" in the "Common Clinical Data Set" for certification to the 2015 Edition to replace the concept of the "care plan field(s), including goals and instructions" which is part of the "Common MU Data Set" in the 2014 Edition. We clarified that we intend "care plan field(s), including goals and instructions" to be a single provider's documentation of their assessment, plan of treatment, goals, and health concerns for the patient, and we stated that this clarification applies for 2014 Edition certification. We proposed this clarification to better align with the terms used in the C–CDA Release 2.0, which includes the "Assessment and Plan Section (V2)," "Assessment Section (V2)," "Plan of Treatment Section (V2)," "Goals Section," and "Health Concerns Section." In previous iterations of the C–CDA, we explained that the "Plan of Treatment Section" was called the "Plan of Care Section," which resulted in confusion on whether the information was intended to represent a single encounter or the synthesis of multiple encounters. For that reason, the "Plan of Care Section" was proposed to be called the "Plan of Treatment Section" to indicate that it is intended to represent a single encounter and not to be confused with the "Care Plan document template."

For certification to the 2015 Edition, we proposed to include in the Common Clinical Data Set "assessment and plan of treatment," "goals," and "health concerns" data in accordance with the C–CDA Release 2.0 "Assessment and Plan Section (V2)" or both the "Assessment Section (V2)" and "Plan of Treatment Section (V2);" the "Goals Section;" and the "Health Concerns Section." We encouraged health IT developers to allow for structured documentation or tagging that would allow a provider to choose relevant pieces of assessment, plan of treatment, goals, and health concerns data that could be synthesized into a comprehensive care plan. We noted that all proposed 2015 Edition certification criteria that reference the "Common Clinical Data Set" (e.g., the "ToC" criterion) would therefore also require a Health IT Module to be able to capture "assessment and plan of treatment," "goals," and "health concerns" data.

Comments. A couple of commenters expressed concern regarding whether this proposal aligned with the C–CDA standard. One commenter found this inclusion to be duplicative since it is captured under "Care Plan Field(s)" and "Problems." A few commenters noted that we should clarify the intent of the "Goals Section" and "Health Concerns

¹⁶⁵ <https://loinc.org/downloads/usage/units>.

Section.” These commenters noted that the “Goals Section” and “Health Concerns Section” of the C–CDA Care Plan document template provide more structure and were originally designed to be used with the Care Plan document template. However, other C–CDA document templates, like CCD, allow for health concerns and goals to be included as a narrative within the “Assessment Section (V2),” “Plan of Treatment Section (V2),” or “Assessment and Plan Section (V2).”

Response. We have reviewed the C–CDA 2.1 standard and believe there is no misalignment with our proposal and that it provides the requisite specificity we described in the Proposed Rule (80 FR 16872). Therefore, we have adopted the specific data elements as proposed (i.e., “Assessment Section (V2)” and “Plan of Treatment Section (V2)” or “Assessment and Plan Section (V2);”

“Goals Section;” and “Health Concerns Section”). We clarify that we will certify Health IT Modules to the “Goals Section” and the “Health Concerns Section” from the Care Plan document template for the purposes of meeting the Common Clinical Data Set definition. Thus, other C–CDA document templates such as CCD, Referral Note, and Discharge Summary would need to be able to exchange the structured “Goals Section” and “Health Concerns Section” in order to meet the Common Clinical Data Set definition.

Sexual Orientation, Gender Identity, and Other Data

We received recommendations for the inclusion of data in Common Clinical Data Set that we did not propose.

Comments. Commenters recommended that we include sexual orientation and gender identity (SO/GI), military history, and nutritional data in

the Common Clinical Data Set definition.

Response. We have not included any of this data in the definition as this was outside the scope of our proposal and, more importantly, inclusion at this time would not give full consideration to the maturity of related standards, the readiness of health IT developers to exchange this data, the clinical relevance of the data, and other considerations for some of the data such as any potential privacy and security concerns. We note, however, that we have taken the intermediate step of including SO/GI data in the 2015 Edition “demographics” criterion, which is a criterion included in the 2015 Edition Base EHR definition. We refer readers to section III.A.3 of this preamble for more information on the 2015 Edition “demographics” criterion and SO/GI data.

Table 8. Common Clinical Data Set		
Data	2014 Edition Standard	2015 Edition Standard
Patient Name	No associated standard.	No associated standard.
Sex	No associated standard.	The standard specified in § 170.207(n)(1) – Birth sex must be coded in accordance with HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor attributed as follows: (1) Male. M (2) Female. F (3) Unknown. nullFlavor UNK
Date of Birth	No associated standard.	No associated standard.
Race	The standard specified in § 170.207(f)(1) – The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity”).	The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).
Ethnicity	The standard specified in § 170.207(f)(1) - The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity”).	The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).
Preferred Language	The standard specified in § 170.207(g)(1) – 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.	The standard specified in § 170.207(g)(2) – Request for Comments (RFC) 5646.
Smoking Status	The standard specified in § 170.207(h) – Smoking status must be coded in one of the following SNOMED CT® codes: (1) Current every day smoker. 449868002 (2) Current some day smoker. 428041000124106	The standard specified in § 170.207(h) – Smoking status must be coded in one of the following SNOMED CT® codes: (1) Current every day smoker. 449868002 (2) Current some day smoker. 428041000124106 (3) Former smoker. 8517006

	(3) Former smoker. 8517006 (4) Never smoker. 266919005 (5) Smoker, current status unknown. 77176002 (6) Unknown if ever smoked. 266927001 (7) Heavy tobacco smoker. 428071000124103 (8) Light tobacco smoker. 428061000124105	(4) Never smoker. 266919005 (5) Smoker, current status unknown. 77176002 (6) Unknown if ever smoked. 266927001 (7) Heavy tobacco smoker. 428071000124103 (8) Light tobacco smoker. 428061000124105
Problems	At a minimum, the standard specified in § 170.207(a)(3) – IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release.	At a minimum, the standard specified in § 170.207(a)(4) - IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.
Medications	At a minimum, the standard specified in § 170.207(d)(2) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.	At a minimum, the standard specified in § 170.207(d)(3) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.
Medication Allergies	At a minimum, the standard specified in § 170.207(d)(2) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.	At a minimum, the standard specified in § 170.207(d)(3) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.
Laboratory Test(s)	At a minimum, the standard specified in § 170.207(c)(2) – Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.	At a minimum, the standard specified in § 170.207(c)(3) – Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52.
Laboratory Value(s)/Result(s)	No associated standard.	No associated standard.
Vital Signs	Height/length, weight, blood pressure, and BMI (no associated vocabulary standard).	The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and in accordance with the standard specified

		<p>in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).</p> <p>§ 170.207(c)(3) – Logical Observation Identifiers Names and Codes (LOINC[®]) version 2.52.</p> <p>§ 170.207(m)(1) – The Unified Code of Units of Measure, Revision 1.9, October 23, 2013.</p> <p><u>Optional.</u> The patient’s BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2-20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.</p>
Care Plan Field(s), including Goals and Instructions	No associated standard.	Not applicable (replaced with Assessment and plan of treatment, goals, and health concerns – see below).
Procedures	<p>At a minimum, the version of the standard specified in § 170.207(a)(3), or § 170.207(b)(2).</p> <p>§ 170.207(a)(3) - IHTSDO SNOMED CT[®] International Release July 2012 and US Extension to SNOMED CT[®] March 2012 Release</p> <p>§ 170.207(b)(2) – The code set specified in 45 CFR 162.1002(a)(5) – The combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and</p>	<p>At a minimum, the version of the standard specified in § 170.207(a)(4), or § 170.207(b)(2).</p> <p>§ 170.207(a)(4) - IHTSDO SNOMED CT[®], U.S. Edition, September 2015 Release</p> <p>§ 170.207(b)(2) – The code set specified in 45 CFR 162.1002(a)(5) – The combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT-4), as maintained and distributed</p>

	<p>distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT-4), as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:</p> <ol style="list-style-type: none"> (1) Physician services. (2) Physical and occupational therapy services. (3) Radiologic procedures. (4) Clinical laboratory tests. (5) Other medical diagnostic procedures. (6) Hearing and vision services. (7) Transportation services including ambulance. <p>For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) - The code set specified in 45 CFR 162.1002(a)(4) – <i>Code on Dental Procedures and Nomenclature</i>, as maintained and distributed by the American Dental Association, for dental services.</p>	<p>by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:</p> <ol style="list-style-type: none"> (1) Physician services. (2) Physical and occupational therapy services. (3) Radiologic procedures. (4) Clinical laboratory tests. (5) Other medical diagnostic procedures. (6) Hearing and vision services. (7) Transportation services including ambulance. <p>For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) - The code set specified in 45 CFR 162.1002(a)(4) – <i>Code on Dental Procedures and Nomenclature</i>, as maintained and distributed by the American Dental Association, for dental services.</p>
Care Team Member(s)	No associated standard.	No associated standard.
Immunizations	Immunization data not included for 2014 Edition certification.	<p>In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4).</p> <p>§ 170.207(e)(3) - HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015</p> <p>§ 170.207(e)(4) - National Drug Code Directory (NDC) – Vaccine NDC Linker, updates through August 17, 2015</p>
Unique Device Identifier(s) (UDIs) for a Patient's Implantable Device(s)	UDI data not included for 2014 Edition certification.	<p>In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).</p> <p>§ 170.205(a)(4) - HL7 Implementation Guide for CDA[®] Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial</p>

		<p>Use, Release 2.1.</p> <p><u>Unique device identifier</u> is defined as it is in 21 CFR 801.3 - means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 830.20 of this chapter. A unique device identifier is composed of:</p> <p>(1) A device identifier --a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and</p> <p>(2) A production identifier --a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:</p> <p>(i) The lot or batch within which a device was manufactured;</p> <p>(ii) The serial number of a specific device;</p> <p>(iii) The expiration date of a specific device;</p> <p>(iv) The date a specific device was manufactured;</p> <p>(v) For an HCT/P regulated as a device, the distinct identification code required by 1271.290(c) of this chapter.</p> <p><u>Implantable device</u> is defined as it is in 21 CFR 801.3 – means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health.</p>
Assessment and Plan of Treatment	Not applicable (refer to care plan field(s), including goals and instructions – see above).	§ 170.205(a)(4) - HL7 Implementation Guide for CDA [®] Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1.
Goals	Not applicable (refer to care plan field(s), including goals and instructions – see above).	In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).

		§ 170.205(a)(4) - HL7 Implementation Guide for CDA [®] Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1.
Health Concerns	Not applicable (refer to care plan field(s), including goals and instructions – see above).	In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4). § 170.205(a)(4) - HL7 Implementation Guide for CDA [®] Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1.

Alignment With Clinical Practice

We requested comment in the Proposed Rule on ways in which we can engage the public to keep the Common Clinical Data Set relevant to clinical practice as the data included in the Common Clinical Data Set may change over time.

Comments. A commenter suggested we limit the use of highly prescriptive criteria, permitting innovation and clinical appropriateness to exist within “guardrails.” Another commenter encouraged us to seek input from provider specialty societies and organizations to ensure the interests of clinicians are properly represented, including concerns about clinical workflows.

Response. We thank commenters for their feedback. We will take these comments under consideration for further development and uses of the Common Clinical Data Set to support interoperability, program alignment, and patient care.

4. Cross-Referenced FDA Definitions

We proposed to adopt in § 170.102 new definitions for “Implantable Device,” “Unique Device Identifier,” “Device Identifier,” and “Production Identifier” as discussed in the Proposed Rule’s sections for the “implantable device list” certification criterion. We proposed to adopt the same definitions already provided to these phrases at 21 CFR 801.3 and emphasized that capitalization was purposefully applied to each word in these defined phrases in order to signal to readers that they have specific meanings.

Comments. Commenters expressed unanimous support for our proposed approach to cross-reference relevant FDA definitions. One commenter recommended that we use the term “identifiers” when referring to Device

Identifier and Product Identifier instead of the term “UDI data.” The commenter contended that this would align better with FDA terminology.

Response. We thank commenters for their support. We are adopting the cross-referenced FDA definitions as proposed. In regard to the recommendation to use the term “identifiers,” we agree that our terminology related to UDIs should more closely align with FDA terminology and the UDI final rule to prevent any unnecessary confusion. Therefore, we have revised our terminology use within this final rule and refer readers to the “implantable device list” certification criterion discussed earlier in this preamble for further details.

IV. Provisions of the Proposed Rule Affecting the ONC Health IT Certification Program

A. Subpart E—ONC Health IT Certification Program

We proposed to replace the term “HIT” with the term “health IT” and to change the name of the “ONC HIT Certification Program” to the “ONC Health IT Certification Program” wherever these references occur in subpart E. In referring to the certification program, we noted that the term “health” is capitalized. We also proposed to remove § 170.553 “Certification of health information technology other than Complete EHRs and EHR Modules” as no longer relevant due to proposals in the Proposed Rule for the ONC Health IT Certification Program that would make the program more open and accessible to health IT beyond EHR technology.

Comments. Commenters were broadly supportive of these proposals.

Response. We have adopted these proposals as proposed.

B. Modifications to the ONC Health IT Certification Program

In the Voluntary Edition proposed rule (79 FR 10929–30) we recited our authority and the history of the ONC Health IT Certification Program. The history includes multiple requests for comment and significant stakeholder feedback on making the certification program more accessible to health IT beyond EHR technology and health care settings and practices not directly tied to the EHR Incentive Programs. With consideration of stakeholder feedback and our policy goals, we attempted to make the ONC Health IT Certification Program more open and accessible through a proposal in the Voluntary Edition proposed rule (79 FR 10918–20) to create “meaningful use” (MU) and non-MU EHR Modules. We determined that our proposal was not the best approach in a subsequent final rule (79 FR 54472–73). Since that rulemaking, the HITPC issued recommendations supporting certification for care/practice settings beyond the ambulatory and inpatient settings.¹⁶⁶ In response, we reconsidered how best to structure the program and make it open and accessible to more types of health IT, health IT that supports a variety of care and practice settings, and programs that may reference the ONC Health IT Certification Program, including Medicaid and Medicare payment programs and various grant programs. In the Proposed Rule, we proposed revisions to the ONC Health IT Certification Program to achieve these goals, including new certification criteria for use cases and health care

¹⁶⁶ http://www.healthit.gov/facilities/sites/faca/files/TransmittalLetter_LTPAC_BH_Certification.pdf and http://www.healthit.gov/facilities/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.

settings beyond the EHR Incentive Programs.

Comments. Most commenters supported the increase in scope of technologies and health care settings to include lab information systems, HISPs, HIEs, LTPAC, behavioral health, and pediatrics. Commenters supported opening the certification program to greater accessibility to more health IT, allowing for greater flexibility and use of a variety of health IT products and services, and advancing interoperability beyond narrowly defined EHR technology. Some commenters, however, opposed a more open ONC Health IT Certification Program and the use of certified health IT beyond the EHR Incentive Programs, including linking forms of Medicare and Medicaid reimbursement to the use of certified health IT.

Response. We disagree with the commenters that do not support a more open ONC Health IT Certification Program and the use of certified health IT beyond the EHR Incentive Programs. We believe the ONC Health IT Certification Program should be open and accessible to more types of health IT, health IT that supports a variety of care and practice settings, and programs beyond the EHR Incentive Programs. We have finalized provisions and adopted 2015 Edition certification criteria to support these goals. As discussed in more detail below in regard to referencing the use of certified health IT, ONC and HHS continue to encourage the use of certified health IT to support interoperability and health information exchange across diverse care and practice settings, including the linking of certified health IT to reimbursement under HHS payment programs.

1. Health IT Modules

We proposed to rename EHR Modules as Health IT Modules by removing the EHR Module definition from the CFR at § 170.102 and adding the “Health IT Module” definition. We proposed this change to be effective with this final rule, and we proposed to make this change applicable for certification to the 2014 Edition and 2015 Edition. We stated that the proposed change would have no substantive impact on the technologies that might be, or have been, certified under the ONC Health IT Certification Program. We also noted that technologies already certified to the 2014 Edition as EHR Modules, and their use to meet the CEHRT definition, would not be affected by this proposal.

Comments. Many commenters strongly supported the removal of “Complete EHR” certification in favor of modular certification. A couple of

commenters requested that we clarify what exactly constitutes a Health IT Module, saying that deviations in this definition will lead to inaccurate assessments of workload requirements and scope of impact to implement a specific certification criterion.

Response. We thank commenters for their feedback. The 2014 Edition Release 2 final rule discontinued the “Complete EHR” certification concept (see 79 FR 54443–45). “Complete EHR” certification will not be available to the 2015 Edition.

The definition of a Health IT Module is any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary (see § 170.102). This essentially means any type of technology that could be certified to one *or more* certification criteria under the ONC Health IT Certification Program. For example, a Health IT Module could be certified to only the 2015 Edition “CPOE—Medications” criterion and the other required mandatory and conditional criteria (*i.e.*, the 2015 Edition “safety-enhanced design,” “quality management system,” “accessibility-centered design,” and applicable privacy and certification criteria). Alternatively, a Health IT Module could be certified to practically all the 2015 Edition certification criteria. While we appreciate commenters’ requests for further specificity for the Health IT Module definition, we believe that this definition affords flexibility for health IT developers and providers in terms of what technologies are presented for certification and to what certification criteria (*e.g.*, technology provided by a HISP that is presented for certification to the 2015 Edition “Direct Project, Edge Protocol, and XDR/XDM” certification criterion (§ 170.315(h)(2)) or an EHR technology presented by a developer for certification to the 2015 Edition “CDS” certification criterion (§ 170.315(a)(9)).

2. “Removal” of Meaningful Use Measurement Certification Requirements

We proposed to *not* require ONC–ACBs to certify Health IT Modules to the 2015 Edition “meaningful use measurement” certification criteria (§ 170.315(g)(1) “automated numerator recording” and § 170.315(g)(2) “automated measure calculation”). We explained that we believe this will make the ONC Health IT Certification more accessible to the certification of health IT for other purposes beyond the EHR Incentive Programs. We also emphasized that this proposed approach would not preclude health IT

developers from seeking certification to § 170.315(g)(1) or (2) in support of their customers’ and providers’ needs related to the EHR Incentive Programs.

Comments. A commenter stated that these criteria and their functionality have been well-established through certification to the 2014 Edition “automated measure calculation” and “automated numerator recording” certification criteria; and therefore, their removal should have minimal effect. Several commenters voiced support for removal of these requirements. One commenter noted that this change will not reduce the requirements for accredited testing laboratories to test nor ONC–ACBs to certify these criteria when a health IT developer elects to certify a product for use in the EHR Incentive Programs. A commenter disagreed with removal of these criteria, stating that this functionality is important for EPs and EHs to meet requirements under the EHR Incentive Programs and for purposes of their own quality improvement efforts.

Response. We have adopted our proposed approach in that we will not require ONC–ACBs to certify Health IT Modules to the 2015 Edition “meaningful use measurement” certification criteria. However, the EHR Incentive Program Stage 3 and Modifications final rule includes a CEHRT definition that will require EPs, eligible hospitals, and CAHs to have health IT certified to these criteria in order to meet the CEHRT definition. Accordingly, we encourage health IT developers supporting providers participating in the EHR Incentive Programs or providers’ quality improvement needs to seek certification to these criteria as appropriate for their Health IT Modules (*e.g.*, a Health IT Module is presented for certification to a criterion that supports a Stage 3 objective with a percentage-based measure and the Health IT Module can meet the “automated numerator recording” criterion or “automated measure calculation” criterion) for their Health IT Module (*e.g.*, the Health IT Module is presented for certification to a criterion that supports a Stage 3 objective percentage-based measure and the Health IT Module can meet the “automated numerator recording” criterion or “automated measure calculation” criterion).

3. Types of Care and Practice Settings

We commented in the Proposed Rule that we had proposed a diverse edition of health IT certification criteria with capabilities included that could support a wide range of providers practicing in various settings. We stated that we

anticipated that we would issue general interoperability guidance for the 2015 Edition when it became final, but that we had no plans to *independently* develop and issue certification “paths” or “tracks” by care or practice setting (e.g., a “LTPAC certification”) because it would be difficult to independently devise such “paths” or “tracks” in a manner that was sure to align with other relevant programs and specific stakeholder needs. We explained that we are best suited for supporting the development of standards for specific settings/use cases and providing technical assistance to both health IT developers and providers about the certification criteria, the standards and capabilities they include, and the processes of the ONC Health IT Certification Program. We stated that we would welcome working with HHS agencies, other agencies, or provider associations, in identifying the appropriate functionality and certification criteria to support their stakeholders, including jointly developing specialized certification “paths” or “tracks.” We noted that such an approach would be consistent with stakeholder feedback we received through rulemaking (79 FR 54473–74) and the HITPC recommendations for us to work with HHS agencies and other agencies.

We sought comment on potential future certification criteria that could include capabilities that would uniquely support LTPAC, behavioral health, or pediatrics care/practice settings, as well as other settings. In particular, we sought comment on whether certification criteria focused on patient assessments for certain settings would be of value to health IT developers and health care providers.

Comments. A commenter suggested that patient assessments should not be included in future certification criteria. A commenter requested that EHR certification standards adequately capture and address data elements necessary to support the home care setting—specifically for durable medical equipment prosthetics, orthotics, and supplies (collectively, DMEPOS). The HITPC listed several entities that may find certification requirements applicable to them, including pharmacy information systems, long-term services and support providers (transport, meals, care management services, etc.), ambulance providers, blood banks, end-stage renal disease facilities, free-standing cancer hospitals, visiting nurse services, outpatient surgical centers, telehealth and monitoring, personal health devices (e.g. bands, watches, monitors), biomedical tech devices (e.g.,

pacemakers), personal health record systems, health and fitness centers, free-standing weight-loss centers. One commenter recommended including standards and capabilities to include e-signatures to the Home Health and Hospice Plans of Treatment.

Multiple commenters suggested that modular certification should follow “tracks” or “pathways” for specialists to identify what they need. Some commenters requested that we publish guidelines as to which criteria are applicable to which care settings. These commenters suggested that “certification tracks” could be established for each different segment of the provider market (laboratories, behavioral health, long-term care, etc.) looking for alignment and interoperability across certification “tracks.” A commenter questioned how we and stakeholders would monitor claims that a set of independently certified Health IT Modules meet the requirements of the path or track.

Response. We appreciate the breadth and diversity of comments on potential future certification criteria that could include capabilities to support different care settings and use cases. Consistent with our request for comment in the Proposed Rule, we will carefully consider these suggestions for future certification criteria.

As mentioned in the Proposed Rule and recited above, we do not intend to develop certification “tracks” or “pathways” for particular provider specialties or settings within this final rule because it would be difficult for us to independently devise such “paths” or “tracks” in a manner that was sure to align with other relevant programs and specific stakeholder needs. We are, however, working with our colleagues within HHS to identify capabilities and certification criteria that support other programs and use cases. We also continue to welcome the opportunity to collaborate with representatives from different provider and specialties societies as well as health IT developers to determine what certification criteria and “tracks” could be identified and developed to support various care and practice settings and particular use cases. We do not anticipate monitoring any developed certification “tracks.” Rather, we anticipate that a program or association, as applicable, would develop any necessary compliance requirements.

4. Referencing the ONC Health IT Certification Program

We stated in the Proposed Rule that the adoption of proposed criteria that support functionality for different care

and practice settings and the proposals to make the ONC Health IT Certification Program open and accessible to more types of health IT and health IT that supports a variety of care and practice settings, would permit further referencing and use of certified health IT. We proceeded to cite other HHS programs that reference certification criteria and the ONC Health IT Certification Program (80 FR 16874).

Comments. One commenter recommended that we not over-specify or over-bundle a singular certification criterion that could cause a mismatch between what a federal program requires and what is defined as a single criterion. Another commenter recommended that we allow for at least 18 months in advance of any compliance dates for providers and health IT developers to successfully test and deploy required certified health IT, stating that an 18-month minimum timeframe is important to ensure that the process provides good design while reducing risks to care and safety.

Response. We agree with the commenter that it is important to try to properly scope a certification criterion so that the capabilities included are consistent with current health IT technologies and design practices. In this regard, we have separated out capabilities that have once been proposed or adopted in a single criterion (e.g., see the “CPOE” criteria or the “application access” (“API”) criteria).

We also agree with the commenter that sufficient lead time must be provided for development, testing, certification, and implementation before certified health IT is required for use. With this final rule and the EHR Incentive Programs Stage 3 and Modifications final rule, providers and health IT developers have 27 months before health IT certified to the 2015 Edition must be used to meet the CEHRT definition adopted in the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**. This timeframe should provide sufficient time for development, testing, certification, and implementation of certified health IT. We plan to continue to work with our colleagues in HHS to ensure that proper lead time is considered with respect to the required use of certified health IT.

We continue to support the use of certified health IT and the ONC Health IT Certification Program to support interoperability and health information exchange across diverse care and practice settings. To note and building on the references we cited in the

Proposed Rule, the HHS interoperability strategy and the encouraged use of certified health IT are mentioned in the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2015 proposed rule (79 FR 45652), the Conditions of Participation for Home Health Agencies proposed rule (79 FR 61185), the CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements proposed rule (80 FR 39844), and the End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program proposed rule (80 FR 37852). The required use of certified health IT continues to be referenced for chronic care management services in CY 2016 Physician Fee Schedule final rule (80 FR 41796). Further, the Mechanized Claims Processing and Information Retrieval Systems (MMIS) proposed rule (80 FR 20464) requires that state MMIS systems align with adopted standards and allow

for interoperability with health information exchanges.

C. Health IT Module Certification Requirements

1. Privacy and Security

We proposed a new approach for privacy and security (P&S) certification to the 2015 Edition. In our past rulemakings, we discussed and instituted two different policy approaches and sought comment on others for ensuring that health IT and providers have privacy and security capabilities while also trying to minimize the level of regulatory burden imposed on health IT developers. With the 2011 Edition, we included an upfront requirement that required Health IT Modules to meet all P&S certification criteria as a condition of certification unless the health IT developer could demonstrate that certain P&S capabilities were either technically infeasible or inapplicable. With the 2014 Edition, we eliminated the upfront requirement for each Health IT Module to be certified against the

P&S criteria in favor of what we thought would better balance the burden potentially posed by our rulemaking. Thus, the P&S criteria were made part of the 2014 Edition Base EHR definition that all EPs, eligible hospitals, and CAHs participating in the EHR Incentive Programs must meet in order to satisfy the CEHRT definition (meaning each provider needed post-certification to ultimately have technology certified to the P&S criteria).

Based on recommendations from the HITSC, in the Proposed Rule, we proposed a revised P&S certification approach for the 2015 Edition so that each certification criterion has a set of appropriate P&S “safeguards” that must be in place. We proposed to require that an ONC-ACB must ensure that a Health IT Module presented for certification to any of the certification criteria that fall into each regulatory text “first level paragraph” category of § 170.315 (e.g., § 170.315(a)) identified below would be certified to either Approach 1 (technically demonstrate) or Approach 2 (system documentation) as follows:

TABLE 9—PROPOSED 2015 EDITION PRIVACY AND SECURITY CERTIFICATION FRAMEWORK

If the Health IT Module includes capabilities for certification listed under:	It will need to be certified to Approach 1 or Approach 2 for each of the P&S certification criteria listed in the “Approach 1” column	
	Approach 1	Approach 2
§ 170.315(a)	§ 170.315(d)(1) (authentication, access control, and authorization), (d)(2) (auditable events and tamper resistance), (d)(3) (audit reports), (d)(4) (amendments), (d)(5) (automatic log-off), (d)(6) (emergency access), and (d)(7) (end-user device encryption).	For each applicable P&S certification criterion not certified for approach 1, there must be system documentation sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces for each applicable privacy and security certification criterion that enable the Health IT Module to access external services necessary to meet the privacy and security certification criterion.
§ 170.315(b)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity).	
§ 170.315(c)	§ 170.315(d)(1) through (d)(3).	
§ 170.315(e)	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(7).	
§ 170.315(f)	§ 170.315(d)(1) through (d)(3) and (d)(7).	
§ 170.315(h)	§ 170.315(d)(1) through (d)(3).	
§ 170.315(i)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	

We explained that under the P&S certification framework we proposed, a health IT developer would know exactly what it needed to do in order to get its Health IT Module certified and a purchaser of a Health IT Module would know exactly what privacy and security functionality against which the Health IT Module had to be tested in order to be certified. We further explained that, because we explicitly proposed which P&S certification criteria would be applicable to the associated criteria adopted in each regulatory text “first level paragraph” category and also

proposed Approach 2, we did not propose to permit the 2011 Edition policy of allowing for a criterion to be met through documentation that the criterion is inapplicable or would be technically infeasible for the Health IT Module to meet.

Comments. Most commenters were supportive of our proposed P&S certification framework, including the HITSC. One commenter recommended that we keep the option for a health IT developer to attest that a certain security criterion is inapplicable or infeasible. Another commenter was concerned that

a health IT developer would have to redundantly certify products that have a shared security infrastructure.

Response. We appreciate the broad support expressed for the proposed framework. We have adopted the P&S certification framework as proposed. As recited above and stated in the Proposed Rule, we continue to believe it is not necessary to permit health IT developers to attest that certain P&S criteria are inapplicable or infeasible because we have specified which P&S certification criteria are applicable to a Health IT Module based on the other adopted

2015 Edition certification criteria for which it is presented for certification to as well as also permitting certification through Approach 2. We clarify that Approach 2 provides health IT developers with the ability to demonstrate through system documentation that products share a security infrastructure, giving developers the option to certify the security infrastructure only once.

Comments. Several commenters provided feedback suggesting which 2015 Edition P&S certification criteria should apply to each grouping of 2015 Edition certification criteria in Table 9 above. Commenters recommended that we should add the:

- “Integrity” certification criterion (§ 170.315(d)(8)) to the clinical certification criteria (§ 170.315(a)) due to transmissions of laboratory data per the proposed “CPOE—laboratory” certification criterion (§ 170.315(a)(2));
- “Amendments” certification criterion (§ 170.315(d)(4)) to the care coordination criteria (§ 170.315(b)) to support patient requested amendments; and
- “Automatic access time-out” certification criterion (§ 170.315(d)(5)) to the clinical quality measures criteria (§ 170.315(c)) since patient health information is evident in many quality measurement implementations.

Response. We have not adopted the commenter’s recommendation to apply the “integrity” certification criterion (§ 170.315(d)(8)) to the clinical certification criteria because we have not adopted the proposed content

exchange functionality for the “CPOE—laboratory” certification criterion. By not adopting the content exchange functionality (LOI standard), testing and certification will not involve the preparation of patient laboratory data for transmission consistent with the proposed standards. Therefore, the “integrity” certification criterion (§ 170.315(d)(8)) does not need to be applied to the category of criteria (*i.e.*, § 170.315(a)).

The application of the “amendment” criterion is not necessary for care coordination. We have made the “amendment” criterion applicable to the “clinical care” category of criteria (*i.e.*, § 170.315(a)). The functionality certified under the “clinical care” category focuses on data capture and is more appropriate for application of the “amendment” criterion, while the “care coordination” category focuses on the transmission of health information and not patient interaction related to amending the record.

We agree with commenters that the “automatic access time-out” criterion should apply to the clinical quality measures criteria for the reasons provided by the commenters and have included it as applicable to § 170.315(c) under the P&S certification framework. As discussed in the “application access to Common Clinical Data Set” section of this preamble, we have adopted and applied new P&S criteria (“trusted connection” (§ 170.315(d)(9)) and “auditing actions on health information” (§ 170.315(d)(10)) to the

three “API” certification criteria as part of the P&S certification framework. These new criteria are derived from the security requirements included in the proposed “API” criterion in the Proposed Rule and have been applied back to the “API” criteria adopted in this final rule.

We have separated out the “patient engagement” category (§ 170.315(e)) by criterion to provide clarity and appropriate application of privacy and security capabilities. In this regard, we do not apply “end-user device encryption” to the “secure messaging” and “patient health information capture” criteria as that was not our intention. We have added the new “trusted connection” criteria to the “patient engagement” category (§ 170.315(e)) to compliment the revisions we made to the “VDT” and “secure messaging” criteria as part of the overall P&S certification framework and to support the functionality included in the “patient health information capture” criterion. Please see the discussions of these criteria earlier in this preamble for further details.

In this final rule, we require that an ONC–ACB must ensure that a Health IT Module presented for certification to any of the certification criteria that fall into each regulatory text “first level paragraph” category of § 170.315 (*e.g.*, § 170.315(a)) identified in Table 10 below is certified to either Approach 1 (technically demonstrate) or Approach 2 (system documentation) as follows:

TABLE 10—FINAL 2015 EDITION PRIVACY AND SECURITY CERTIFICATION FRAMEWORK

If the Health IT Module includes capabilities for certification listed under:	It will need to be certified to Approach 1 or Approach 2 for each of the P&S certification criteria listed in the “Approach 1” column	
	Approach 1	Approach 2
§ 170.315(a)	§ 170.315(d)(1) (authentication, access control, and authorization), (d)(2) (auditable events and tamper resistance), (d)(3) (audit reports), (d)(4) (amendments), (d)(5) (automatic log-off), (d)(6) (emergency access), and (d)(7) (end-user device encryption).	For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation sufficiently detailed to enable integration with external services necessary to meet the criterion.
§ 170.315(b)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity).	
§ 170.315(c)	§ 170.315(d)(1) through (d)(3) and (d)(5)*.	
§ 170.315(e)(1)	§ 170.315(d)(1) through (d)(3), (d)(5), (d)(7), and (d)(9) (trusted connection)*.	
§ 170.315(e)(2) and (3)	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(9)*.	
§ 170.315(f)	§ 170.315(d)(1) through (d)(3) and (d)(7).	
§ 170.315(g)(7), (8) and (9)*	§ 170.315(d)(1) and (d)(9); and (d)(2) or (d)(10) (auditing actions on health information)*.	
§ 170.315(h)	§ 170.315(d)(1) through (d)(3).	

* Emphasis added to identify additions to the framework as compared to the Proposed Rule.

We clarify that of the adopted 2015 Edition certification criteria, only the privacy and security criteria and the

criteria specified in § 170.315(g)(1) through (6) are exempt from the P&S certification framework due to the

capabilities included in these criteria, which do not implicate privacy and security concerns.

In order to be issued a certification, a Health IT Module would only need to be tested once to each applicable privacy and security criterion identified as part of Approach 1 or Approach 2 so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification, except for the certification of a Health IT Module to § 170.315(e)(1) “VDT” and (e)(2) “secure messaging.” For each criterion, a Health IT Module must be separately tested to § 170.315(d)(9) because of the specific capabilities for secure electronic transmission and secure electronic messaging included in each criterion, respectively.

Comments. We received several comments requesting clarification on our proposal to allow a health IT developer to certify for P&S criteria using system documentation sufficiently detailed to enable integration with external services necessary to meet P&S certification criteria (Approach 2). One commenter requested clarification regarding how an ONC-ACB would verify that documentation was sufficient to implement the interface. Another commenter pointed out that interfaces to external systems may carry an additional cost. Other commenters questioned whether the lack of standardized interfaces will lead to security gaps or be an impediment to information sharing.

Response. System documentation for Approach 2 requires a clear description of how the external services necessary to meet the applicable P&S criteria would be deployed and used. We note that Approach 2 is one of two options that provide health IT developers more certification flexibility. Health IT developers and their customers have the discretion to seek certification to the approach (Approach 1 or 2) that best meets their needs, taking into account efficiencies, costs, and security concerns. We further note that the actual implementation of privacy and security capabilities is outside the scope of certification, but in most instances, is guided by applicable federal and state privacy and security laws. We are supportive of the unencumbered exchange of health information and note that certified capabilities should not be implemented in a way that precludes health information sharing.

Comments. A commenter requested clarification on how a health IT developer could guarantee certain functionality, particularly end-user device encryption.

Response. Certification ensures that a Health IT Module can meet the

capabilities of a certification criterion. However, it does not ensure the appropriate implementation of the capabilities. For example, in the context of a Health IT Module’s certification to the “VDT” criterion (§ 170.315(e)(1)), additional required certification to the “end-user device encryption” criterion is intended to apply to the storage actions that the Health IT Module is programmed to take (*i.e.*, creation of temp files, cookies, or other types of cache approaches) and not an individual or isolated user action to save or export a file to their personal electronic storage media.

Comments. A commenter stated that the P&S certification framework is more specific than the approach prescribed in the HIPAA Security Rule. Another commenter stated that we should not name specific encryption and hashing standards because the information security risk landscape is constantly evolving.

Response. The P&S certification framework focuses on the capabilities of health IT certified to the 2015 Edition. It is not designed nor could it align with each covered entity’s responsibilities under the HIPAA Security Rule, which focus on a risk-based approach to security. We note, however, that the adoption of health IT certified to the 2015 Edition under the P&S framework may support a provider’s compliance with the HIPAA Security Rule and other federal and state privacy and security laws. We do not require specific standards for encryption and hashing. Rather, we require any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014.¹⁶⁷ For hashing, we require any hashing algorithm with security strength equal to or greater than SHA-2 as identified by NIST as an approved security function in that publication.

2. Design and Performance (§ 170.315(g))

We proposed to revise § 170.550 to add paragraph (g), which would require ONC-ACBs to certify Health IT Modules to certain proposed certification criteria under § 170.315(g). We proposed to require ONC-ACBs to certify Health IT Modules to § 170.315(g)(3) (safety-enhanced design) and § 170.315(g)(6) (Consolidated CDA creation performance) consistent with the requirements included in these criteria.

¹⁶⁷ <http://csrc.nist.gov/publications/fips/fips140-2/fips1402annexa.ps>.

We noted that paragraph (g) also includes a requirement for ONC-ACBs to certify all Health IT Modules presented for certification to the 2015 Edition to § 170.315(g)(4) (quality system management) and (g)(8) (accessibility-centered design). We explained that the proposed certification requirements for § 170.315(g)(3) and (4) maintain the policy approach established with certification to the 2014 Edition (see § 170.550(f)(2) and (3)), which ensures Health IT Modules, as applicable, are certified to these specific safety and quality certification criteria. We also explained that the proposed certification requirement for § 170.315(g)(6) is associated with the new “Consolidated CDA creation performance” criterion we proposed for the 2015 Edition. We reiterated that the requirement is similarly designed to ensure that Health IT Modules (with Consolidated CDA creation capabilities within their scope) are also certified to the “Consolidated CDA creation performance” criterion. We noted the proposed certification requirements for § 170.315(g)(8) were associated with the new “accessibility-centered design” criterion we proposed for the 2015 Edition, which patterned the certification approach of the 2014 Edition “quality system management” criterion.

Comments. Commenters supported the proposed revisions to § 170.550.

Response. We thank commenters for their support. We have added paragraph (g) to § 170.550 as proposed with a minor cross-reference revision that points to the 2015 Edition “accessibility-centered design” criterion codified in § 170.315(g)(5) instead of proposed paragraph (g)(8).

D. Principles of Proper Conduct for ONC-ACBs

1. “In-the-Field” Surveillance and Maintenance of Certification

We proposed new requirements for “in-the-field” surveillance and maintenance of certification under the ONC Health IT Certification Program. The requirements would clarify and expand ONC-ACBs’ existing surveillance responsibilities, including the responsibility to perform surveillance of certified capabilities “in the field.” We explained that in-the-field surveillance is necessary to provide assurance to customers, implementers, and users that health IT certified on behalf of ONC will continue to meet the requirements of its certification when it is implemented and used in a production environment.

Through our proposal, we sought to promote greater consistency, transparency, and rigor in the surveillance of certified capabilities and to provide stakeholders with greater clarity and predictability regarding this important aspect of the ONC Health IT Certification Program.

Our proposal defined in-the-field surveillance and specified certain conditions and procedures under which ONC-ACBs would be required to initiate in-the-field surveillance of certified Complete EHRs and certified Health IT Modules. We delineated separate requirements for surveillance based on complaints or other information about potential non-conformities (“reactive surveillance”) and for surveillance based on a random sampling approach (“randomized surveillance”). In addition, we specified certain corrective action plan requirements and procedures that would apply in the context of randomized surveillance. ONC-ACBs would also be required to report the results of their in-the-field surveillance to the National Coordinator on at least a quarterly basis and, separately, to report corrective action plan information to the publicly accessible open data CHPL detailed in our separate proposal “Open Data Certified Health IT Product List (CHPL).”

To implement the new requirements for in-the-field surveillance outlined in the Proposed Rule, we proposed to add § 170.556 (In-the-field surveillance and maintenance of certification for health IT) and amend § 170.503 (ONC-AA Ongoing Responsibilities) and § 170.523 (ONC-ACB Principles of Proper Conduct).

Definition and Principles for In-the-Field Surveillance

We proposed to explicitly define in-the-field surveillance to mean an ONC-ACB’s assessment of whether a certified Complete EHR or certified Health IT Module to which it has issued a certification continues to conform to the certification’s requirements when the health IT is implemented and in use in the field. This assessment would require an ONC-ACB to assess the technology’s capabilities in a production environment and, where applicable, would be based on the use of the capabilities with protected health information (PHI), unless the use of test data were specifically approved by the National Coordinator. We explained that such surveillance could be performed through an in-person site visit or by remote observation. We solicited comments on these and other approaches to in-the-field surveillance.

Comments. We received mixed comments on our focus on “in-the-field” surveillance. The commenters who supported our focus on surveillance of certified health IT capabilities “in the field” expressed strong support for our proposal to define and establish clear and explicit expectations for in-the-field surveillance. Commenters stated that clearer and more rigorous requirements for in-the-field surveillance would promote confidence in certifications issued on behalf of ONC and significantly improve the reliability and performance of certified health IT. One ONC-ACB specifically endorsed these requirements and our commitment to ensure that certified health IT capabilities function for providers in their local offices and hospitals in the same manner demonstrated by the health IT developer in a controlled testing environment. Another ONC-ACB specifically supported the concept of in-the-field surveillance in the context of complaint-based surveillance, which has been a focus of the current approach to in-the-field surveillance developed through our annual surveillance guidance.

Several commenters described specific challenges they or their members had encountered with certified health IT capabilities that failed to perform in an acceptable manner when implemented in the field. For example, one commenter stated that it had witnessed several instances in which certified health IT that had successfully demonstrated the ability to send a single standards-compliant continuity of care document in a controlled testing environment could not “scale” and send multiple standards-compliant continuity of care documents when deployed in a production environment. Commenters stated that our proposed in-the-field surveillance requirements would help identify and address these kinds of apparent non-conformities.

Response. We thank these commenters for their feedback. They underscore our view of the importance of in-the-field surveillance for ensuring that providers and other stakeholders can rely on certifications issued on behalf of ONC. This basic assurance protects the integrity of the ONC Health IT Certification Program and federal health IT investments because it enables customers, implementers, and users to select appropriate technologies and capabilities; identify potential implementation or performance issues; and implement certified health IT in a predictable, reliable, and successful manner.

While ONC-ACBs are already required to conduct in-the-field surveillance as part of their overall surveillance approaches, we agree with these commenters that establishing more explicit and more rigorous requirements will promote greater consistency and clarity regarding ONC-ACBs’ responsibilities for conducting in-the-field surveillance, which will in turn improve the reliability and performance of certified health IT and help identify and address potential non-conformities.

Comments. Other commenters, mostly health IT developers, were less supportive of in-the-field surveillance. They cautioned that some factors that may affect the performance of certified health IT—such as how the health IT is configured, implemented and adopted by users and integrated with other health IT components as part of complex, local implementations—may be challenging for ONC-ACBs to evaluate or could in some cases be beyond the scope of a health IT’s certification. Some commenters asserted that ONC-ACBs may lack the sophistication or expertise to distinguish certification non-conformities from other factors that may cause certified health IT to perform differently in the field than in a controlled testing environment. In particular, current certification requirements may be tested with an established workflow (often the health IT developer’s “optimal workflow”) but made available to users with additional workflow and implementation options. According to these commenters, an ONC-ACB unfamiliar with a particular variation could incorrectly regard it as a non-conformity. Separately, a few commenters asserted that end-users with whom an ONC-ACB would conduct in-the-field surveillance may lack the necessary skill and knowledge to properly demonstrate certified health IT capabilities, or may be susceptible to “leading questioning” (presumably by the ONC-ACB conducting the surveillance).

Response. We appreciate the concerns raised by commenters and acknowledge that in-the-field surveillance presents unique challenges. However, we disagree with the suggestion that ONC-ACBs lack the sophistication or expertise to perform in-the-field surveillance or to do so in a reliable and objective manner.

Under the ONC Health IT Certification Program, ONC-ACBs’ surveillance approaches must include the use of consistent, objective, valid, and reliable methods, subject to the ongoing supervision of the ONC-AA.

(§ 170.503(e)(2)). In addition, the requirements for in-the-field surveillance established by this final rule build on those with which ONC-ACBs are already familiar, including the requirements for in-the-field surveillance that have existed since the establishment of the Permanent Certification Program in 2011.¹⁶⁸ Since that time, it is our experience that ONC-ACBs have become increasingly adept at analyzing the performance of certified health IT in the field, including working with developers and end-users to identify the causes of reported problems and to distinguish certification issues from other factors that may affect the performance of certified health IT. For all of these reasons, we are confident that ONC-ACBs will be able to meet their responsibilities for conducting in-the-field surveillance.

Comments. Given the unique challenges associated with in-the-field surveillance, some commenters suggested that, in addition to observing how certified capabilities operate in a production environment, ONC-ACBs should be permitted to use other methods to inform their evaluation of technology in the field. For example, the ONC-AA stated that attempting to replicate reported problems in a controlled testing environment may provide a better basis for identifying a suspected non-conformity than relying on in-the-field observations. Separately, several commenters, including the ONC-AA, suggested that ONC-ACBs should work closely with health IT developers in analyzing complaints and other information about potential non-conformities. The commenters stated that including developers in the surveillance process would be important because ONC-ACBs may not be familiar with a developer's particular technology and implementations. Moreover, health IT developers may have internal complaint and quality management programs that could be leveraged to provide insight into problems and their causes.

Response. We appreciate these suggestions, which are consistent with the approach to in-the-field surveillance we envisioned in the Proposed Rule. We agree with commenters that the assessment of certified health IT in a production environment may require ONC-ACBs to employ a variety of

methodologies and approaches. While these must include, they need not be limited to, observing the performance of certified capabilities in the field. Thus in addition to observing how capabilities function in the field, an ONC-ACB might supplement its field observations with information related to the certified technology gleaned from other sources of surveillance, such as user surveys, reviewing developers' complaint logs and defect tickets (including the developer's root cause analysis and resolution of tickets), and attempting to replicate reported problems in a controlled environment. These and other appropriate investigative and diagnostic techniques may help ONC-ACBs more effectively target and conduct their field assessments and inform their overall assessments of certified health IT capabilities in the field.

We also agree that ONC-ACBs should, where appropriate, involve health IT developers in their surveillance activities. For example, an ONC-ACB could require a health IT developer to provide technical assistance to the ONC-ACB in understanding and analyzing variations not seen during the testing and certification process and other complexities. ONC-ACBs could also require or permit health IT developers to assist in analyzing and determining the causes of issues, provided such assistance does not compromise the ONC-ACB's independence or the requirements of its accreditation.

Comments. Several commenters requested additional clarity regarding the precise standards that would govern an ONC-ACB's assessment of certified capabilities in the field. Some commenters stated that the standards articulated in the Proposed Rule did not provide a sufficiently objective basis for determining that certified health IT, once implemented, no longer conforms to the requirements of its certification. Some commenters requested that we provide detailed guidance and bright-line rules to guide ONC-ACBs in making these determinations.

Response. While we understand the desire for bright-line rules, we do not think it practicable or a useful exercise to attempt to anticipate and prescribe detailed rules for every conceivable situation in which an ONC-ACB may discover a non-conformity during its surveillance of technology in the field. In practice, certified health IT may be integrated with a wide range of other systems, processes, and people and may be customized and used in many different ways. These circumstances, which are inherent to the production

environment, are too numerous and varied to anticipate or to reduce to simple rules of universal application.

In light of these complexities, we identified the basic principles that would guide an ONC-ACB's surveillance of certified health IT in the field. (80 FR 16877). In response to commenters' requests for additional clarity, we further elaborate on these principles below. We believe that with these additional clarifications, the principles we have identified will provide ONC-ACBs with clear and predictable guidance and ensure that in-the-field surveillance is conducted in a fair, reliable, and consistent manner across all health IT products and implementations.

Analysis and Examples of Non-Conformities in the Field

Comments. Some commenters asked us to clarify whether an ONC-ACB's evaluation of certified health IT capabilities in the field must be limited to those aspects of the health IT that were tested in a controlled environment. In this connection, a few commenters stated that certain factors—such as how certified capabilities are made available to and implemented by users in the field—are beyond the scope of certification under the ONC Health IT Certification Program and therefore cannot give rise to a “non-conformity.”

Response. An ONC-ACB's assessment of certified health IT in the field is not limited to aspects of the technology that were tested in a controlled environment. Rather, an ONC-ACB must consider the unique circumstances and context in which the certified health IT is implemented and used in order to properly assess whether it continues to perform in a manner that complies with its certification.

Testing is an important part of an ONC-ACB's overall analysis of health IT under the ONC Health IT Certification Program. For practical reasons, however, testing focuses on particular use cases and necessarily reflects assumptions about how capabilities will be implemented and used in practice. Thus while test results provide a preliminary indication that health IT meets the requirements of its certification and can support the capabilities required by the certification criteria to which the technology was certified, that determination is always subject to an ONC-ACB's ongoing surveillance, including the ONC-ACB's evaluation of certified capabilities in the field. Indeed, a fundamental purpose of in-the-field surveillance is to identify deficiencies that may be difficult to anticipate or that may not become

¹⁶⁸ 76 FR 1282 (clarifying our expectation under the Permanent Certification Program that an “ONC-ACB would focus its surveillance activities on whether the Complete EHRs and/or EHR Modules it has certified continue to perform ‘in the field’ . . . as they did when they were certified.”); see also ONC, *ONC Health IT Certification Program, Program Policy Guidance #13*-01.

apparent until after certified health IT is implemented and used in a production environment. That purpose would be entirely frustrated if an ONC-ACB's assessment of technology in the field were confined to those aspects of the technology's performance specifically delineated in test procedures.

Comments. Several commenters stated that, depending on the circumstances, certified health IT that has been implemented in the field may be unable to demonstrate certified capabilities for reasons that are beyond the health IT developer's control. For example, users may customize certified health IT capabilities in ways that could not be anticipated by the developer or that conflict with the developer's explicit instructions regarding the proper implementation and configuration of its technology. These and other factors beyond the control of a developer should not, according to these commenters, be grounds for a determination of non-conformity.

Response. We recognize there may be instances in which certified health IT cannot successfully demonstrate implemented capabilities for reasons that the developer cannot reasonably influence or control. We clarify that, as discussed below, these circumstances would be beyond the scope of the health IT's certification and would not give rise to a non-conformity.

A non-conformity arises when certified health IT fails to conform to the requirements of its certification under the ONC Health IT Certification Program. Those requirements take several forms and may apply to aspects of the design and performance of technology as well as the responsibilities of health IT developers. In particular, certified health IT must be able to support the capabilities and uses required by applicable certification criteria, and developers must make such capabilities available in ways that enable them to be implemented and used in production environments for their intended purposes.¹⁶⁹ Developers

¹⁶⁹ Most certification criteria permit technology to be designed and made available to users in any way that meets the outcomes required by the criteria. Several certification criteria, however, also prescribe specific requirements for how certified capabilities are designed or made available to users. For example, the safety-enhanced design criterion (§ 170.315(g)(3)) requires developers to apply user-centered design processes to the capabilities referenced in that criterion during the design and development of certified health IT. Other certification criteria require developers to identify specific design or performance characteristics of their technology, such as the quality management system (§ 170.315(g)(4)) and accessibility-centered design standard or law (§ 170.315(g)(5)) used in the development, testing, implementation, and maintenance of the capability.

must also comply with additional program requirements as a condition of certification.¹⁷⁰

While these requirements vary based on the specific certification criteria or program requirements at issue, all of them focus on the responsibilities of health IT developers and those aspects of their technology that they can reasonably influence or control. Accordingly, if an ONC-ACB finds that health IT, as implemented in the field, cannot demonstrate required capabilities in a compliant manner, the ONC-ACB must determine the reasons for the failure, including the roles of the technology as well as the health IT developer, users, and other parties. If the ONC-ACB finds that the developer or its technology were a substantial cause of the failure, the ONC-ACB would conclude that the health IT does not meet the requirements of its certification. By contrast, if the ONC-ACB finds that the failure was caused exclusively by factors far removed from the control or responsibility of the developer, the ONC-ACB would regard those factors as beyond the scope of the health IT's certification and would not find a non-conformity. The following contrasting scenarios provide an example of these requirements in practice.

• *Scenario A:* An ONC-ACB initiates in-the-field surveillance of a Health IT Module certified to the clinical decision support certification criterion at § 170.315(a)(9). The ONC-ACB observes the use of the capability at a location at which it has been implemented. The ONC-ACB observes as a user unsuccessfully attempts to access user diagnostic or therapeutic reference information for a patient as required by the criterion. The ONC-ACB then performs a series of troubleshooting and diagnostic exercises with the provider and the developer of the certified Health IT Module. After additional fact-finding and analysis, the ONC-ACB concludes that the failure of the technology to perform as expected was caused by the failure to implement a routine update of the linked referential clinical decision support component of the Health IT Module. Under the terms of the provider's agreement with the

¹⁷⁰ In addition to the requirements established by adopted certification criteria, a Complete EHR or Health IT Module's certification is also conditioned on the health IT developer's compliance with certain program requirements that are necessary to the basic integrity and effectiveness of the ONC Health IT Certification Program. These requirements include, for example, the mandatory disclosure requirements (§ 170.523(k)(1)) and the requirements related to displaying the ONC Certified HIT Certification and Design Mark (§ 170.523(1)).

developer, the developer was solely responsible for implementing routine updates in return for an annual maintenance fee, which the provider had paid in full.

Based on these facts, the ONC-ACB would find a non-conformity because the failure of the certified health IT to function as expected was due solely to the actions of the developer that prevented the user from accessing capabilities to which the health IT was certified.

• *Scenario B:* An ONC-ACB initiates in-the-field surveillance of a Health IT Module certified to the clinical decision support certification criterion § 170.315(a)(9). The ONC-ACB observes the use of the capability at a location at which it has been implemented. The ONC-ACB observes as a user unsuccessfully attempts to view user diagnostic or therapeutic reference information for a patient as required by the criterion. Upon further evaluation, the ONC-ACB learns that the provider had notified the developer that it did not wish to purchase or sublicense the standard clinical reference information bundled with the developer's clinical decision support technology and requested instead that the developer integrate its technology with the provider's preferred third-party database of clinical reference information. The developer agreed to integrate the third-party database information as requested, but in writing advised the provider that, because the developer did not have a sublicensing agreement in place with the third-party vendor, the provider would be responsible for obtaining and maintaining the necessary licenses for access to the third-party vendor's database. The developer successfully integrated the third-party database information as requested, and the certified capabilities performed as expected using the third-party database information for several months prior to the ONC-ACB's surveillance. However, at the time of the surveillance, access to the third-party database information had been temporarily suspended because of the provider's failure to pay several outstanding invoices from the third-party vendor—the result of an oversight in the provider's accounting department. Because of the suspension in service, the technology, which was otherwise performing as certified, was unable to retrieve and display user diagnostic and therapeutic reference information.

Based on these facts, the ONC-ACB would not find a non-conformity because, while the technology was unable to perform required capabilities in the field, the failure was caused by

factors far removed from the control or responsibility of the developer. Indeed, the developer took care to warn the provider that, while the technology could be customized to support third-party database information, the provider would be responsible for maintaining any necessary licenses for access to the third party database information.

Comments. Some commenters stated that contractual restrictions or other limitations on the use of a developer's certified health IT should be treated as a non-conformity, while several other commenters asked for additional guidance on this issue.

Response. As the scenarios above illustrate, because developers sell and license certified technology in many different ways and often in conjunction with many other related products and services, an ONC-ACB's evaluation of technology in the field will necessarily require a consideration of the manner in which the developer makes its certified technology and associated capabilities available to customers and users, including a consideration of implementation options, contractual terms, and other factors that could affect the performance of the capabilities in the field. For example, an ONC-ACB would find a non-conformity were it to determine that a developer had imposed restrictions or limitations¹⁷¹ on its technology (or the use of its technology) that substantially interfered with users' ability to access or use certified capabilities for any purpose within the scope of the technology's certification, as in the following scenarios.

- *Scenario C:* An ONC-ACB initiates in-the-field surveillance of a Health IT Module certified to the data export criterion at § 170.315(b)(6). The ONC-ACB observes the use of the capability at a location at which it has been implemented. The ONC-ACB observes as a user unsuccessfully attempts to create a set of export summaries using the required standard for patients whose information is stored in the technology. The ONC-ACB contacts the health IT developer, which explains that to utilize the data export capability, a user must load a series of coded instructions into the technology using the developer's proprietary scripting language. However, the developer restricts the ability of users to access training materials or instructions that would allow them to acquire the necessary knowledge and expertise to perform this function.

Based on these facts, the ONC-ACB would find a non-conformity. Specifically, the developer has restricted access to training materials and instructions that are needed to access and capability and successfully use it to achieve the technical outcomes contemplated by § 170.315(b)(6). Indeed, as the scenario illustrates, the restriction effectively prevents a user from using the data export capability at all. As such, the technology no longer conforms to the requirements of its certification.

- *Scenario D:* An ONC-ACB initiates in-the-field surveillance of a Health IT Module certified to the data export criterion at § 170.315(b)(6). The ONC-ACB observes the use of the capability at a location at which it has been implemented. The user is able to successfully create a set of export summaries for patients in real time but is unable to configure the technology to create a set of export summaries based on a relative time and date (e.g., the first of every month at 1:00 a.m.). The ONC-ACB contacts the health IT developer, which explains that the ability to create export summaries based on a relative time and date is an "advanced functionality" that the developer has disabled by default. The developer will only enable the functionality if a customer specifically requests it.

Based on these facts, the ONC-ACB would find a non-conformity. Specifically, the developer has placed a technical limitation on its technology by disabling and thus preventing users from accessing functionality within the scope of the technology's certification to the data export capability. Indeed, the ability to create a set of export summaries based on a relative time and date is expressly required by § 170.315(b)(6)(iii)(B)(2). That a customer must specifically request that the developer turn on the functionality is a substantial interference with a user's ability to access and use this aspect of the certified capability. As such, the technology no longer conforms to the requirements of its certification.

Comments. Some commenters asked whether a developer's failure to disclose known material limitations or types of costs associated with its certified health IT would give rise to a non-conformity. Several commenters assumed that it would and stated that, together with the more meaningful transparency and disclosure requirements we proposed, assessing the effect of developers' disclosures on the performance of certified health IT in the field would promote greater transparency and reliability of certified health IT capabilities and help mitigate business

practices that limit or interfere with access to certified health IT capabilities.

Response. Under the expanded transparency and disclosure requirements at § 170.523(k)(1), which are discussed in section IV.D.2 of this preamble, a health IT developer must disclose all known material limitations and types of costs associated with its certified health IT. The failure to disclose this information is a violation of an explicit certification program requirement (§ 170.523(k)(1)) and thus constitutes a non-conformity. The disclosure violation may also give rise to a separate non-conformity in the event that the failure to disclose the required information has substantially impaired, or would be likely to substantially impair, the ability of one or more users (or prospective users) to implement or use the developer's certified health IT in a manner consistent with its certification.

As an example, if the developer in Scenario D above failed to disclose the technical limitation described in that scenario, the ONC-ACB would find a non-conformity to the disclosure requirements at § 170.523(k)(1). This determination would be warranted because the developer's failure to disclose the limitation could substantially interfere with the ability of a user or prospective user to implement the data export capability in a manner consistent with the technology's certification to § 170.315(b)(6).¹⁷²

Given the risk of non-conformity created by the failure of a developer to disclose the kinds of material information described above, and the concomitant requirement for ONC-ACBs to evaluate such disclosures in order to properly evaluate certified technology in the field, we have finalized elsewhere in this final rule our proposal to expand and clarify the types of information that developers are required to disclose as a condition of certification under the ONC Health IT Certification Program. We discuss these disclosure requirements in detail in section IV.D.2 of this preamble, "Transparency and Disclosure Requirements."

For the foregoing reasons, and with the clarifications discussed above, we have finalized as proposed the definition of in-the-field surveillance at § 170.556(a).

Reactive Surveillance

We proposed to clarify and add to ONC-ACBs' responsibilities for

¹⁷² The ONC-ACB would also find a separate non-conformity to § 170.315(b)(6), for the reasons explained in connection with Scenario D.

¹⁷¹ Potential restrictions and limitations are discussed in detail in section IV.D.2 of this preamble, "Transparency and Disclosure Requirements."

conducting “reactive surveillance”—that is, surveillance of certified health IT initiated on the basis of complaints or other indications that the health IT does not conform to the requirements of its certification. We proposed to create an explicit duty for an ONC-ACB to initiate such surveillance whenever it becomes aware of facts or circumstances that call into question the continued conformity of a certified Complete EHR or certified Health IT Module to the requirements of its certification (including conformity both to applicable certification criteria as well as to other requirements of certification, such as the disclosure requirements at § 170.523(k)(1)). Further, we proposed that whenever an ONC-ACB initiates reactive surveillance, it would be required, as a matter of course, to assess the health IT developer’s compliance with the disclosure requirements at § 170.523(k)(1).

Comments. Many commenters agreed with the proposed requirements for reactive surveillance. Commenters stated that strengthening surveillance, including in-the-field surveillance, based on complaints and other information about the real-world performance of capabilities would provide greater assurance to providers that they will in fact be able to implement and use the capabilities to which health IT has been certified. The ONC-AA and ONC-ACBs largely supported our proposed reactive surveillance requirements and urged us to focus primarily on refining this aspect of in-the-field surveillance and not the proposed randomized surveillance requirements.

Some commenters, mostly ONC-ACBs, sought greater clarity regarding the interaction between the proposed reactive surveillance requirements and ONC-ACBs’ existing responsibilities for conducting reactive and other forms of surveillance pursuant to the requirements of their accreditation to ISO/IEC 17065 and authorization to issue certifications under the ONC Health IT Certification Program. Relatedly, several commenters noted that the proposed duty to initiate reactive surveillance would require in all cases that such surveillance take place in the field; these commenters regarded this as an overly broad requirement that could unnecessarily supplant other forms of “traditional” surveillance that, depending on the circumstances, may be more effective and less burdensome.

Response. We thank commenters for their thoughtful comments on this aspect of our proposal. In consideration of these comments and the additional

comments summarized below, we are finalizing the reactive surveillance requirements at § 170.556(b), subject to the revisions discussed below. The revisions address the request from commenters for clarification of the interaction between the proposed reactive surveillance requirements and ONC-ACBs’ existing obligations to conduct reactive surveillance.

The proposed reactive surveillance requirements focused primarily on an ONC-ACB’s duty to initiate surveillance of certified health IT *in the field*. Specifically, we stated that an ONC-ACB would be required to initiate *in-the-field* surveillance whenever it becomes aware of facts or circumstances that call into question health IT’s continued conformity to the requirements of its certification (80 FR 16878). However, we agree with the observation of several commenters that requiring ONC-ACBs to initiate in the field surveillance in all cases would be unnecessarily prescriptive. In some cases, an ONC-ACB will be able to investigate and evaluate a putative non-conformity just as effectively by using traditional forms of surveillance that do not depend on observing certified health IT capabilities in the field. For example, an ONC-ACB may identify and substantiate non-conformities through conventional desk-audits followed by re-testing of Health IT Modules in a controlled environment. As another example, an ONC-ACB may perform an audit of a developer’s complaint processes to identify potential non-compliance with the requirements of ISO/IEC 17065. Similarly, an ONC-ACB may audit a developer’s website and other communications to identify potential non-compliance with the disclosure requirements (§ 170.523(k)(1)), the Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark (§ 170.523(l)), or other certification requirements.

Because our intent was to build upon—not supplant—these traditional forms of surveillance, we have revised the requirements at § 170.556(b) as follows. Under § 170.556(b), an ONC-ACB has a duty to initiate reactive surveillance—including, as necessary, in-the-field surveillance—whenever it becomes aware of facts or circumstances that would cause a reasonable person to question a certified Complete EHR or certified Health IT Module’s continued conformity to the requirements of its certification. Such conformity includes both ongoing conformity to applicable certification criteria as well as compliance with other requirements of certification, including the disclosure

requirements for health IT developers at § 170.523(k)(1).

Whether reactive surveillance must include in-the-field surveillance or may employ other methods is governed by the definition and principles for in-the-field surveillance described earlier in this preamble and codified at § 170.556(a), including the nature of the suspected non-conformity and the adequacy of other forms of surveillance under the circumstances. In most cases, the need to evaluate the certified health IT in the field will be obvious from the nature of the suspected non-conformity. For example, if a problem with a certified health IT capability is reported to arise only in connection with a specific local implementation option, an ONC-ACB would likely need to observe the relevant capabilities in the field in order to fully analyze the cause of the problem and determine whether it is the result of a non-conformity. In other cases, the need for in-the-field surveillance may become apparent only after other surveillance methods and techniques have failed to isolate the cause of the problem.

In-the-field surveillance may also be necessary to determine a developer’s compliance with certification program requirements, such as the mandatory disclosure requirements at § 170.523(k)(1). While non-compliance with these requirements may often be established from complaints and a review of a developer’s disclosures, certain kinds of undisclosed limitations on the capabilities of certified health IT may need to be confirmed through in-the-field surveillance of the technology, or may not be discovered at all except upon observing the operation of certified capabilities in the field.

Comments. A number of commenters asked us to articulate more precise standards for when an ONC-ACB would be required to initiate reactive surveillance. Some of these commenters stated that ONC-ACBs would not be able to consistently apply the standard set forth in the Proposed Rule, which would require an ONC-ACB to initiate reactive surveillance whenever it becomes aware of facts or circumstances that would cause a reasonable person to question a certified Complete EHR or certified Health IT Module’s continued conformity to the requirements of certification.

Response. As requested by commenters, we provide the following additional guidance on the circumstances that would trigger an ONC-ACB’s duty to initiate reactive surveillance under the requirements at § 170.556(b).

In determining whether to initiate reactive surveillance, an ONC-ACB must consider and weigh the volume, substance, and credibility of complaints and other information received against the type and extent of the alleged non-conformity, in light of the ONC-ACB's expertise and experience with the particular capabilities, health IT, and certification requirements at issue. For example, if an ONC-ACB receives a number of anonymous complaints alleging general dissatisfaction with a particular certified Health IT Module, the ONC-ACB is not required to initiate surveillance (though it would not be precluded from doing so). In contrast, if an ONC-ACB receives several complaints alleging, for example, that a particular certified Health IT Module is unable to electronically create a set of export summaries in accordance with the data export certification criterion at § 170.315(b)(6), the ONC-ACB must initiate surveillance of the Health IT Module unless a reasonable person in the ONC-ACB's position would doubt the credibility or accuracy of the complaints. A reasonable basis for doubt might exist if the ONC-ACB had recently responded to the very same issue and determined through in-the-field surveillance of the Health IT Module at several different locations that the reported problem was due to a "bug" arising from an unsupported use of the Health IT Module that the developer had specifically cautioned users about in advance.

An ONC-ACB's decision to initiate reactive surveillance must also take into account complaints and other information indicating whether a health IT developer has disclosed all known material information about certified capabilities, as required by § 170.523(k)(1). The failure to disclose this information calls into question the continued conformity of those capabilities because it creates a substantial risk that existing and prospective users will encounter problems implementing the capabilities in a manner consistent with the applicable certification criteria. Thus in the example above, if the complaints received by the ONC-ACB suggested that the developer knew about but failed to disclose the data export issue to users, the ONC-ACB would be required to initiate in-the-field surveillance of the certified Health IT Module to verify whether the developer had failed to disclose known material information and, if so, whether the failure to disclose that information prevented users from reasonably implementing

and using the data export capability in accordance with the requirements of the certification criterion at § 170.315(b)(6).

We believe the foregoing principles and examples will provide sufficient clarity and practical guidance for ONC-ACBs regarding their responsibilities for conducting reactive surveillance pursuant to § 170.556(b). If necessary, we will issue additional guidance to ONC-ACBs to assist them in conducting such surveillance in a consistent, objective, and reliable manner.

Comments. A commenter suggested that reactive surveillance should be based solely on complaints submitted directly to ONC-ACBs. The commenter stated that ONC-ACBs "can't be expected to keep ears to the ground" to monitor the trade press, user group message boards, blogs, analyst reports, and other sources of information, which may not be credible. Another commenter asked us to clarify that in determining whether to initiate reactive surveillance, ONC-ACBs would be required to consider complaints from persons other than providers and users of certified health IT (such as public health agencies and other recipients of electronic health information that may not themselves use certified health IT).

Response. Under the requirements adopted in this final rule, an ONC-ACB has a duty to initiate reactive surveillance whenever it becomes aware of facts or circumstances that call into question the continued conformity of health IT to which it has issued a certification. We do not prescribe new requirements for ONC-ACBs to proactively monitor any particular source of information (such as the trade press or user forums), as ONC-ACBs are already required obtain and synthesize information about certified health IT from multiple sources.

Regardless of the form of the information or how it comes to an ONC-ACB's attention, if the information suggests that health IT the ONC-ACB has certified may no longer conform to the requirements of its certification, the ONC-ACB is required to initiate surveillance. For example, an ONC-ACB may become aware of a potential non-conformity through user surveys and other "behind-the-scenes" surveillance of users and products. Or an ONC-ACB may become aware of a potential non-conformity while auditing a developer's website and other disclosures. ONC will also share information with ONC-ACBs, which may well come from the trade press and other sources. And, of course, an ONC-ACB will receive complaints from a variety of sources, including, as one commenter suggested, entities such as

public health agencies that may not be certified health IT users. All of this information would compose the facts and circumstances of which an ONC-ACB is aware and is required to consider in determining whether to initiate surveillance.

Randomized Surveillance

In addition to reactive surveillance, we proposed to require ONC-ACBs to initiate in-the-field surveillance on a "randomized" basis for the certification criteria prioritized by the National Coordinator. For those prioritized certification criteria, an ONC-ACB would be required each calendar year to randomly select at least 10% of the Complete EHRs and Health IT Modules to which it has issued a certification. The ONC-ACB would then be required to initiate in-the-field surveillance of each such certified Complete EHR or certified Health IT Module at the lesser of 10 or 5% of locations at which the technology is implemented and in use in the field. The locations would be selected at random, subject to certain sampling considerations and limited exclusions described in the Proposed Rule.

We stated that randomized surveillance would enable ONC-ACBs to identify non-conformities that are difficult to detect through complaint-based or other reactive forms of surveillance. Randomized surveillance would also enable an ONC-ACB to detect patterns of non-conformities that indicate a more widespread or recurring problem requiring a comprehensive corrective action plan. We proposed that a pattern of non-conformity would exist if an ONC-ACB found that a certified Complete EHR or certified Health IT Module failed to demonstrate conformity to any prioritized certification criterion at 20% or more of the locations surveilled. Upon such a finding, the ONC-ACB would deem the certified Complete EHR or certified Health IT Module "deficient" and impose a corrective action plan on the developer of the certified Complete EHR or certified Health IT Module. We specified certain elements and procedures that would be required for such corrective action plans.

Comments. We received strong support for our proposal to require ONC-ACBs to perform "randomized" surveillance as part of their in-the-field surveillance approach. Several commenters who supported our proposal urged us to minimize the associated disruption and other burdens for providers who participate in randomized surveillance.

A number of commenters—including the ONC-AA and the ONC-ACBs—raised concerns regarding this aspect of our proposal. The ONC-ACBs estimated that performing randomized surveillance on 10% of certified products, even at the relatively small number of locations specified in the Proposed Rule, would as much as double the total cost of certification and divert an inordinate amount of time and resources away from other important certification and surveillance activities. Meanwhile, commenters including the ONC-AA doubted that the proposed sample size would be sufficient to detect patterns of non-conformities or to determine with any degree of confidence how widespread a particular non-conformity may be. In this connection, commenters pointed out that surveilling a randomly selected certified Complete EHR or certified Health IT Module at the lesser of 10 or 5% of locations at which the technology is installed may not yield a statistically significant result. For example, if an ONC-ACB were to randomly select a Health IT Module installed at 40 locations, the ONC-ACB would only be required to perform in-the-field surveillance at 2 locations. The ONC-AA stated that performing surveillance of certain certified capabilities, such as interoperability or privacy and security, at only 2 locations would be insufficient to identify all but the grossest non-conformities.

Some commenters felt that it was premature to codify a specific approach to randomized surveillance and that we should instead create a “pilot study” or allow ONC-ACBs to continue to experiment with approaches to randomized surveillance in order to gauge the willingness of providers to participate, potential methodologies, and the costs and benefits of this type of surveillance.

Response. Randomized surveillance is an important aspect of an ONC-ACB’s overall approach to in-the-field surveillance. In addition to exposing problems that may not surface through complaints and other forms of surveillance, randomized surveillance will encourage developers to proactively address issues and will also encourage providers to participate in and become familiar with in-the-field surveillance of certified health IT. However, we acknowledge that the proposed randomized surveillance requirements could place a significant burden on ONC-ACBs and divert resources and energy away from other equally important aspects of our proposal, including more rigorous in-the-field surveillance of certified health IT based

on complaints and other evidence of potential non-conformities. Balancing these considerations, we are persuaded that starting with a less ambitious approach to randomized surveillance will allow us to refine this aspect of surveillance over time and will provide the best path to achieving our overall goal of strengthening in-the-field surveillance and making it more meaningful.

Accordingly, we have revised the proposed randomized surveillance requirements as follows. First, we have reduced the annual sample size for randomized surveillance. Instead of 10% of all certified Complete EHRs and certified Health IT Modules, an ONC-ACB must perform randomized surveillance on 2% of certified Complete EHRs or certified Health IT Modules each year. Based on current data on the CHPL, we estimate this could require ONC-ACBs to perform randomized surveillance of up to 24 products per calendar year (depending on the total number of products the ONC-ACB has certified, which we expect will increase with the addition of Health IT Modules certified to the 2015 Edition). We believe this new minimum threshold will provide additional insight and experience related to randomized surveillance. This specific baseline will establish a randomized surveillance program that advances our policy aims while reducing the burden of randomized surveillance for all stakeholders and making this initial approach more manageable for ONC-ACBs. That being said, we intend to continually review surveillance results and experiences to determine whether and how to increase this threshold over time (e.g., whether an incrementally rising threshold over time would be appropriate and effective). We also intend to pursue and investigate other avenues that could add feedback to (and be combined with) this surveillance process. For example, we will explore other kinds of tools, such as those that may be able to be used directly by health care providers to test and report how their products performed. Overall, and over the long-term, we believe that other approaches can and should be included to complement the randomized in-the-field surveillance performed by ONC-ACBs.

Second, while an ONC-ACB must perform surveillance of randomly selected certified Complete EHRs and certified Health IT Modules in the field, we no longer specify a minimum number of locations at which the ONC-ACB will be required to conduct such surveillance. This revision reflects commenters’ insight that requiring an

ONC-ACB to surveil the technology at the lesser of 5% or 10 locations, as we had proposed, could be simultaneously both burdensome and yet unlikely to yield statistically significant or generalizable results. It also reflects our recognition, underscored by the comments, that well-established methodologies and standards for post-market surveillance used in other industries typically focus on conformity testing of discrete products or components in isolation and thus provide little guidance for formulating appropriate sampling and statistical methods under the ONC Health IT Certification Program. Given the lack of suitable reference models in other industries, we agree with commenters that this particular aspect of an ONC-ACB’s randomized surveillance approach would benefit from additional experience and piloting. Thus we intend to work with ONC-ACBs and the ONC-AA and issue guidance as necessary to refine these aspects and ensure the use of consistent and reliable methods across ONC-ACBs and their surveillance approaches.

Finally, we have eliminated the concept of “deficient surveillance results” and instead applied the proposed corrective action plan requirements across-the-board to all types of surveillance and confirmed non-conformities. Thus, if an ONC-ACB performs randomized surveillance for a certified Complete EHR or certified Health IT Module and confirms a non-conformity, it must institute a corrective action plan under § 170.556(d) and report related information to the open data CHPL, as required by § 170.556(e)(3). This requirement applies regardless of whether the non-conformity meets the 20% “deficiency threshold” described in the Proposed Rule. These changes are described in more detail below in our responses to the comments on these aspects of our proposal.

We have finalized these revisions at § 170.556(c)–(e).

Comments. A number of commenters suggested that we specify additional details regarding the random sampling approach that ONC-ACBs must follow when selecting certified Complete EHRs and certified Health IT Modules for randomized surveillance and, separately, when selecting the locations at which the technology will be surveilled in the field. Commenters noted that under a purely random sampling approach, an ONC-ACB would be equally likely to select a Complete EHR or Health IT Module with relatively few installations or users as one with many installations or users.

To maximize the value of randomized surveillance for providers and other stakeholders, commenters suggested that we require ONC-ACBs to weigh the selection of products based on the number of installed locations, users, or other factors.

Commenters also suggested we clarify or specify additional requirements related to the number and types of locations at which an ONC-ACB must surveil certified Complete EHRs and certified Health IT Modules that it has randomly selected for in-the-field surveillance. One commenter stressed the importance of ensuring random selection of and diversity in the providers and locations selected for surveillance. Another commenter suggested that an ONC-ACB's approach to selecting locations would need to vary depending on the type of implementation (e.g., local versus hosted systems).

Response. We thank commenters for their feedback on potential random sampling and other considerations for randomized surveillance. While we do not explicitly adopt any additional sampling or methodological constraints beyond those we proposed, we agree with many of the commenters' suggestions and intend to work with ONC-ACBs and the ONC-AA to incorporate these and other elements in their approaches to randomized surveillance, consistent with the basic parameters established by this final rule and discussed in more detail below.

In consideration of the comments provided, we have determined that an ONC-ACB's selection process under randomized surveillance will adhere to the following requirements. On an annual basis the ONC-ACB must ensure that it meets the threshold sample size, which is initially being established at 2% of all of the Complete EHRs and Health IT Modules to which the ONC-ACB has issued a certification. The ONC-ACB must randomly select products from those to which it has issued a certification, but is permitted to implement appropriate weighting and sampling considerations. After an ONC-ACB has randomly selected a product for surveillance, for each product selected, the ONC-ACB must select a random sample of one or more locations at which the ONC-ACB will initiate in-the-field surveillance of the certified Complete EHR or certified Health IT Module's prioritized capabilities. At both stages of the selection process, an ONC-ACB must ensure that every product selected and every provider location at which the product is in use has a chance of being randomly selected for in-the-field surveillance (unless a

product is excluded from selection because it was already selected for randomized surveillance within the last 12 months). This prospect, that any product and location may be selected at random, is the essence of a "random sampling" approach and is a central feature of randomized surveillance because it ensures that all health IT developers' products and implementations are potential candidates for in-the-field surveillance. The possibility that any product may be surveilled at any provider location will encourage developers to proactively address issues and improve the real-world performance and reliability of health IT capabilities across all customers.

Consistent with these principles, we clarify that an ONC-ACB's selection of products and locations need not be random in the absolute sense of assigning an equal probability of selection to every product or location in the pool. Indeed, for the reasons stated by commenters, there may be strong justifications for assigning different probabilities or "weights" to products or locations based on a variety of factors that are relevant to maximizing the value and impact of randomized surveillance activities for providers and other stakeholders. For example, when selecting products for randomized surveillance, the ONC-ACB could assign greater weight to products that are more widely adopted and used so as to increase the likelihood that the products surveilled will include at least some products with a large number of installations and users. This would increase the overall impact of the ONC-ACB's surveillance activities by increasing the likelihood of discovering and addressing non-conformities that affect a large number of providers and users. As another example, when randomly selecting locations at which to perform in-the-field surveillance for any particular product, an ONC-ACB might ensure that no two locations selected are under the common ownership or control of a single person or entity, thereby addressing the concerns raised by commenters regarding the diversity of providers and locations selected for randomized surveillance.

To avoid any misinterpretation of the phrases "randomly select" and "selected at random," we have clarified the regulation text at § 170.556(c)(2) and § 170.556(c)(4)(ii) to allow for appropriate weighting and sampling considerations in the random selection of products and locations, respectively.

Finally, we note that under the ONC Health IT Certification Program, it is an ongoing responsibility of the ONC-AA

to ensure that the surveillance approaches used by ONC-ACBs, including the selection processes and methodologies for randomized surveillance discussed above, include the use of consistent, objective, valid, and reliable methods. (§ 170.503(e)(2)). We intend to work closely with the ONC-AA and the ONC-ACBs to ensure that such methods are in place and to identify and incorporate appropriate best practices and elements that serve the policies of this final rule.

Comments. Commenters pointed out that while ONC-ACBs may be able to randomly select locations at which to conduct in-the-field surveillance, they cannot compel a provider to grant access to its health care facility or to cooperate in the surveillance of its certified health IT. At the same time, providers may be reluctant to allow ONC-ACBs to perform in-the-field surveillance because of concerns about granting access to PHI. One ONC-ACB stated that it had experienced difficulties securing cooperation from providers in connection with its existing surveillance activities and therefore questioned whether providers would be willing to participate in additional surveillance, especially when conducted at random rather than in response to a complaint or identified issue.

Given these concerns, some commenters suggested that ONC-ACBs should not be required to conduct randomized surveillance unless providers are also required to participate in such surveillance as a condition of participation in the EHR Incentive Programs or other programs. Alternatively, other commenters suggested that we provide exceptions and other flexibility for ONC-ACBs in the event that a provider is selected for but does not cooperate with an ONC-ACB's in-the-field surveillance of the provider's certified health IT. Several commenters requested clarity on our expectations for providers' role as participants in in-the-field surveillance, especially randomized surveillance.

Response. We appreciate commenters' concerns and acknowledge that randomized surveillance presents unique challenges. In particular, we recognize that some providers who are selected for randomized surveillance may not cooperate with an ONC-ACB's efforts. Moreover, depending on the number of locations at which a particular product is in use, a lack of cooperation from providers or end-users could prevent the ONC-ACB from conducting in-the-field surveillance of that product altogether.

Because we agree that an ONC-ACB should not be penalized in such situations, we clarify that where an ONC-ACB makes a good faith effort but is nevertheless unable to complete in-the-field surveillance at a particular location for reasons beyond its control, the ONC-ACB may exclude the location and substitute another location that meets the random selection requirements described above. Similarly, in the event that the ONC-ACB exhausts all available locations for a particular certified Complete EHR or certified Health IT Module, the ONC-ACB may exclude that Complete EHR or Health IT Module and substitute another randomly selected Complete EHR or Health IT Module. In the case of exhaustion, we clarify that the excluded certified Complete EHR or Health IT Module would be counted towards the minimum number of products an ONC-ACB is required to randomly surveil during the calendar year surveillance period. We emphasize, however, that an ONC-ACB must carefully and accurately document its efforts to complete in-the-field surveillance for each product and at each location. The ONC-AA would be expected to review this documentation to ensure that ONC-ACBs have met the required random selection requirement and have made a good faith effort to perform in-the-field surveillance prior to excluding any product or location from randomized surveillance. We believe that these revisions—combined with the reduced minimum sample size for in-the-field surveillance and the clarifications noted above regarding the number of locations at which an ONC-ACB must observe capabilities in the field—will mitigate the concerns raised by commenters and make randomized surveillance more manageable for ONC-ACBs, providers, and developers.

It is our expectation that providers will cooperate with an ONC-ACB's authorized surveillance activities, including the surveillance of certified health IT in the field. While we understand that some providers may be reluctant to grant ONC-ACBs access to PHI, we point out that providers who commented on our proposal overwhelmingly supported and urged us to finalize requirements for the surveillance of certified health IT in the field (i.e., in production environments in which the technology is implemented and used). Such surveillance will only be successful if providers are actively engaged and cooperate with ONC-ACBs' surveillance activities, including by granting access to and assisting ONC-ACBs to observe the performance

of production systems. We also note that, in consultation with the Office for Civil Rights, we have clarified that under the "health oversight agency" exception of the HIPAA Privacy Rule, a healthcare provider is permitted to disclose PHI to an ONC-ACB during the course of authorized in-the-field surveillance activities, without patient authorization and without a business associate agreement.¹⁷³

Comment. One commenter, an ONC-ACB, stated that some health IT developers have resisted providing the ONC-ACB with a complete list of the health IT developers' users. The commenter asked us to clarify that health IT developers have an obligation to abide by and support an ONC-ACB's surveillance requirements, including furnishing complete and up-to-date user lists upon request.

Response. We expect an ONC-ACB to require, as a condition of certification, that health IT developers furnish to the ONC-ACB upon request, accurate and complete customer lists, user lists, and other information that the ONC-ACB determines is necessary to enable it to carry out its surveillance responsibilities. We note that even under ONC-ACB's existing annual surveillance plans, access to accurate customer and user lists is essential to an ONC-ACB's ability to contact users for reactive surveillance and to conduct surveys and other activities necessary to obtain and synthesize information about the performance of certified health IT. Therefore, if a health IT developer refuses to provide this information to an ONC-ACB, the ONC-ACB may regard the refusal as a refusal to participate in surveillance under the ONC Health IT Certification Program and institute appropriate procedures, consistent with the ONC-ACB's accreditation to ISO 17065, to suspend or terminate the health IT developer's certification.

Corrective Action Requirements; Reporting of Surveillance Results and Corrective Action Information

In the Proposed Rule, we stated that if an ONC-ACB found a pattern of nonconformity—defined as a failure to demonstrate conformity to any prioritized certification criterion at 20% or more of the locations surveilled—the ONC-ACB would be required to treat the certified Complete EHR or certified Health IT Module as "deficient." This finding would also trigger special requirements for corrective action plans and the reporting of that information to

the open data CHPL. Specifically, the ONC-ACB would have to contact the developer of the certified Complete EHR or certified Health IT Module and require the developer to submit a proposed corrective action plan to the ONC-ACB within 30 days of the date that the developer was notified by the ONC-ACB of the "deficient" finding. The ONC-ACB would be responsible for prescribing the form and content of corrective action plans and for developing specific procedures for submission and approval, with guidance from ONC to promote consistency across ONC-ACBs.

Comments. Many commenters supported our proposal to specify certain required elements and procedures for corrective action. Several commenters asked us to clarify whether these requirements would apply to non-conformities confirmed through reactive and other forms of surveillance and, if not, what if any corrective action would be required for those non-conformities. Several commenters urged us to apply the same standards for corrective action to all types of surveillance and non-conformities. Commenters pointed out that the reasons for imposing such requirements apply with equal force to all confirmed non-conformities, not only those identified through randomized surveillance and meeting the proposed 20% threshold. In particular, requiring corrective action plans and related public reporting for only some non-conformities and not others would be difficult to square with our stated goals of improving transparency and accountability for health IT developers and ONC-ACBs. Commenters also questioned whether the proposed approach would best achieve our patient safety goals. When an ONC-ACB confirms a non-conformity in the context of reactive surveillance, it may not know whether the problem is widespread unless and until it conducts more extensive randomized surveillance of a large sample of the potentially affected certified Complete EHR or certified Health IT Module. For reasons described earlier, ONC-ACBs may have difficulty at this time conducting randomized surveillance on the necessary scale. Applying the corrective action plan and related reporting requirements to all types of surveillance and confirmed non-conformities would alert users to these potential concerns.

Response. Our goal for these requirements was to ensure that health IT users, implementers, and purchasers would be alerted to potential non-conformities in a timely and effective manner, consistent with the patient

¹⁷³ See ONC Regulation FAQ #45 [12-13-045-1], available at <http://www.healthit.gov/policy-researchers-implementers/45-question-12-13-045>.

safety, program integrity, and transparency objectives described in the Proposed Rule. But as the comments make clear, the proposed requirements would only partially serve those goals. As commenters pointed out, there is no principled reason to apply the proposed corrective action plan exclusively to non-conformities identified in the context of the proposed randomized surveillance approach. Moreover, the comments suggest that prescribing different corrective action plan requirements in this context than for other types of non-conformities (which would be governed by an ONC-ACB's general responsibility to require corrective action per its accreditation to ISO 17065) would likely create significant and unnecessary confusion.

Particularly in light of the reduced emphasis on randomized surveillance in comparison to the Proposed Rule, we are persuaded that our policy objectives will be better served by requiring the same approach to corrective action across the board. Thus we have finalized the proposed requirements for corrective action plans for all certified Complete EHRs and certified Health IT Modules for which an ONC-ACB confirms a non-conformity, whether that non-conformity is confirmed through randomized, reactive, or any other form of surveillance under the ONC Health IT Certification Program.

For similar reasons, we have finalized the proposed reporting requirements for corrective action plans and extended these requirements to all cases in which an ONC-ACB confirms a non-conformity and subsequently approves a corrective action plan. Requiring the uniform submission of this information will promote transparency and alert health IT users, implementers, and purchasers to potential conformity issues in a more timely and effective manner. These reporting requirements are discussed further below in our response to the comments on this aspect of our proposal and also in our discussion of the "Open Data CHPL" requirements found elsewhere in this preamble.

Comment. A commenter suggested that in addition to making information about corrective action plans available on the CHPL, we should require health IT developers to notify affected users of the corrective action, similar to the requirements for breach notification under the HIPAA Rules. The commenter stated that many providers do not regularly check the CHPL and therefore may not be made aware of problems in a timely manner.

Response. We appreciate the commenter's suggestion that health IT

developers who are subjected to a corrective action plan should be required to notify affected and potentially affected users of identified non-conformities and deficiencies. We already proposed to require developers to describe in their corrective action plans both an assessment of how widespread an identified non-conformity might be and how the developer planned to address the non-conformity both at the specific locations at which surveillance occurred and more generally at other potentially affected locations (80 FR 16879). Requiring developers to describe how they will notify affected and potentially affected users of the extent of the problem and their plans to address it is a natural extension of these requirements and will help alert stakeholders to potential non-conformities in a timely and effective manner, which was one of the stated purposes of these requirements (80 FR 16884).

Accordingly, we have added as a requirement of all corrective action plans approved by an ONC-ACB that the developer identify a process for ensuring that all affected and potentially affected customers and users are alerted to identified non-conformities and deficiencies, as applicable. This process must describe in detail: How the developer will assess the scope and impact of the problem, including identifying all potentially affected customers; how the developer will promptly ensure that all potentially affected customers are notified of the problem and plan for resolution; how and when the developer will resolve issues for individual affected customers; and how the developer will ensure that all issues are in fact resolved.

To ensure adherence to these requirements for notification and resolution across a developer's customer base, and to the other requirements of the approved corrective action plan, we have added as an additional requirement of all corrective action plans approved by an ONC-ACB that the developer attest to having completed all required elements of the plan, including the requirements for alerting customers and users described above.

Comments. Many commenters supported our proposals to improve the reporting and submission of surveillance results. Several commenters stated that requiring ONC-ACBs to submit corrective action plan information to the publicly accessible open data CHPL would provide customers and users with valuable information about the performance of certified health IT while significantly

enhancing transparency and accountability for health IT developers and ONC-ACBs.

Some commenters, including several health IT developers, objected to the reporting of corrective action plan information to the publicly accessible Open Data CHPL. Some commenters felt that information about non-conformities should not be made public unless and until the developer of the certified Complete EHR or certified Health IT Module at issue has been given a full and fair opportunity to contest the ONC-ACB's determination, including whether the developer was responsible or "at fault" for the non-conformity. Other commenters stated that such information should never be made public because it is bound to lack important context, could be misinterpreted, or would not offer substantial value to health IT customers and users. Separately, some commenters raised concerns regarding the reporting of proprietary or competitively sensitive information.

A few commenters suggested that to reduce reporting burden or improve the efficacy of the open data CHPL, we limit the types of information about corrective action that an ONC-ACB would be required to submit. One commenter suggested that the reporting of corrective action plan information be limited to 2015 Edition certified health IT and that reporting of surveillance results be limited to twice a year instead of quarterly. The commenter stated that these changes would reduce burden and enable us to assess the costs of these reporting requirements.

Response. We agree with commenters that requiring ONC-ACBs to report surveillance results to the National Coordinator on a quarterly basis will significantly improve our ability to respond to problems and provide timely and accurate information stakeholders.

With regard to the reporting of corrective action plan information to the open data CHPL, we understand the concerns raised by some commenters but believe that it is both necessary and appropriate to require ONC-ACBs to submit this information. The public safety, transparency, and program integrity rationales for requiring timely and public reporting of this information are compelling. In comparison, and contrary to the assertions of some commenters, making this information available is not likely to cause customers and users to draw inaccurate or unfair conclusions about a health IT developer or its certified technology. By definition, this information will only be required when an ONC-ACB has confirmed a non-conformity and

required a health IT developer to take corrective action. Thus the ONC-ACB will have completed its review of the relevant facts and circumstances, including those raised by the developer in the course of the surveillance of its certified Complete EHR or certified Health IT Module. ONC-ACBs are required to make such determinations in accordance with their accreditation to ISO 17065 and with the Principles of Proper Conduct for ONC-ACBs, subject to ongoing supervision by the ONC-AA. Moreover, as stated in the Proposed Rule, when the developer has provided an explanation of the deficiencies identified by the ONC-ACB as the basis for its determination, the ONC-ACB must include the developer's explanation in its submission to the open data CHPL. Thus developers will be able to note any objections and provide any additional context or information that may be relevant to interpreting the results of the surveillance and the ONC-ACB's findings and conclusions.

We are confident that the concerns of some commenters regarding disclosure of proprietary or sensitive information will be adequately addressed through appropriate safeguards implemented at the discretion of ONC-ACBs. ONC-ACBs should not submit to the open data CHPL any information that is in fact legally privileged or protected from disclosure. ONC-ACBs may also implement other appropriate safeguards, as necessary, to protect information they believe should not be reported to a publicly available Web site. However, we caution ONC-ACBs to ensure that such safeguards are narrowly tailored and consistent with our goal of promoting the greatest possible degree of transparency with respect to certified health IT and the business practices of certified health IT developers. ONC-ACBs are required to accurately report the results of their surveillance and to explain in detail the facts and circumstances on which their conclusions are based. Similarly, health IT developers are required to cooperate with these efforts and may not prevent or seek to discourage an ONC-ACB from reporting the results of its authorized surveillance activities. We note that while the ONC Health IT Certification Program is a voluntary one, developers who choose to participate agree to comply with certification program requirements, including reporting requirements designed to ensure transparency and accountability for all participants and stakeholders.

We decline to limit the requirements for more frequent reporting of surveillance results to the National

Coordinator and the submission of corrective action plan information to the open data CHPL to 2015 Edition certified health IT. The public safety, transparency, and program integrity reasons for requiring the reporting of this information apply to all, and not only 2015 Edition, certified health IT. However, we do agree that the reporting of corrective action information should be limited to the types of information that will be useful to customers and users, consistent with the goals of reporting this information to the open data CHPL explained above. We have therefore revised § 170.523(f)(1)(xxii) and (f)(2)(xi) to limit reporting to the following subset of information:

- The specific certification requirements to which the technology failed to conform, as determined by the ONC-ACB;
- A summary of the deficiency or deficiencies identified by the ONC-ACB as the basis for its determination of non-conformity;
- When available, the health IT developer's explanation of the deficiency or deficiencies;
- The dates surveillance was initiated and completed;
- The results of randomized surveillance, including pass rate for each criterion in instances where the Health IT Module is evaluated at more than one location;
- The number of sites that were used in randomized surveillance;
- The date of the ONC-ACB's determination of non-conformity;
- The date on which the ONC-ACB approved a corrective action plan;
- The date corrective action began (effective date of approved corrective action plan);
- The date by which corrective action must be completed (as specified by the approved corrective action plan);
- The date corrective action was completed; and
- A description of the resolution of the non-conformity or non-conformities.

Comments. We proposed that an ONC-ACB would have to require a health IT developer to submit a proposed corrective action plan within 30 days of being notified of an ONC-ACB's non-conformity determination and to complete an approved corrective action plan within 6 months of such notice. One commenter stated that this timeline was much too long and that developers should not be able to market health IT as certified for 6 months while they correct a non-conformity. Another commenter stated that the 30 day timeline was too short because it would not allow sufficient time for the developer to understand and investigate

the issues and respond to the ONC-ACB's preliminary findings.

Response. We agree with the commenter that a developer should be able to complete an approved corrective action plan within a substantially shorter timeframe than we proposed.

We clarify that the 30 day period for submitting a proposed corrective action plan would begin to run only after an ONC-ACB has issued a non-conformity determination. In our experience, ONC-ACBs already work with health IT developers and users to investigate potential non-conformities prior to issuing a final determination. Because this back-and-forth will have occurred prior to the ONC-ACB's non-conformity determination, we believe that a developer should be able to submit a proposed corrective action plan within 30 days of being notified of the ONC-ACB's non-conformity determination under § 170.556(d)(1). Similarly, if after 90 days of notifying the developer of a non-conformity under § 170.556(d)(1), the ONC-ACB cannot approve a corrective action plan because the developer has not submitted a revised proposed corrective action plan in accordance with § 170.556(d)(4), the ONC-ACB must initiate suspension procedures. Finally, an ONC-ACB must initiate suspension procedures when it has approved a corrective action plan but the developer fails to comply with all of the requirements of the plan within the time specified therein. We have revised § 170.556(d)-(e) to reflect these requirements.

Effective Date and Applicability of Requirements

At the time of this Proposed Rule, ONC-ACBs had submitted their annual surveillance plans for calendar year 2015, which include their existing approaches and methodologies for randomized surveillance. To minimize disruption to ONC-ACBs' current surveillance activities, we proposed to make the requirements for randomized surveillance effective beginning on January 1, 2016. We said this would provide time for ONC-ACBs to implement these requirements in their annual surveillance plans and incorporate additional guidance and clarification from ONC and the ONC-AA as necessary. All other proposed surveillance requirements would be effective immediately. We requested comment on whether this timeline and plan for implementation was appropriate and on ways to minimize disruption and ensure that the requirements and purpose of this proposal are timely and effectively achieved.

Comments. Some commenters, including the ONC-AA and an ONC-ACB, suggested that we specify a single January 1, 2016 effective date for all proposed surveillance requirements in order to allow ONC-ACBs to effectively and consistently implement these requirements in their annual surveillance plans for the calendar year 2016 surveillance period. Another commenter, also an ONC-ACB, stated that it would have difficulty implementing the randomized surveillance requirements for calendar year 2016 and suggested that the requirements be postponed until January 1, 2017. Yet another commenter felt that the timeline for implementing the proposed requirements should be more aggressive.

One ONC-ACB suggested that the proposed requirements for in-the-field surveillance be applied only to 2015 Edition certified health IT so that ONC-ACBs could implement the requirements prospectively in new contracts with health IT developers.

Response. We believe that the proposed timeline for implementation is reasonable. Given the significantly reduced scope of randomized surveillance in comparison to the Proposed Rule, we are confident that ONC-ACBs will be able to complete randomized surveillance requirements over the course of the calendar year 2016 surveillance period. We also believe that ONC-ACBs will be able to implement the other requirements established by this final rule during the 90 days between its publication and effective date. Accordingly, ONC-ACBs must comply with all new requirements by the effective date of this final rule. We will provide guidance to ONC-ACBs regarding updates to their annual surveillance plans for calendar year 2016 and, as necessary, regarding other aspects of surveillance affected by this final rule.¹⁷⁴

We decline to adopt the commenter's suggestion to limit the requirements for in-the-field surveillance and maintenance of certification to only 2015 Edition certified health IT. The need to assure that certified health IT conforms to the requirements of its certification is applicable to all health

IT certified under the ONC Health IT Certification Program, not just technology certified to the new 2015 Edition. Thus, as proposed, we have finalized the in-the-field surveillance and maintenance of certification requirements for all Health IT Modules certified to either the 2015 Edition or the 2014 Edition. With respect to Complete EHRs, because we have discontinued Complete EHR certification with the 2015 Edition, we have finalized these requirements for all Complete EHRs certified to the 2014 Edition. We note that Complete EHR certification to the 2014 Edition has and will continue to occur as providers may use health IT certified to the 2014 Edition to meet the CEHRT definition at least through 2017 based on the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**.

2. Transparency and Disclosure Requirements

We proposed to revise the Principles of Proper Conduct for ONC-ACBs to require greater and more effective disclosure by health IT developers of certain types of limitations and additional types of costs that could interfere with the ability to implement or use health IT in a manner consistent with its certification. We stated that these additional disclosure requirements were necessary to ensure that existing and potential customers, implementers, and users of certified health IT are fully informed about these implementation considerations that accompany capabilities certified under the ONC Health IT Certification Program.

Our proposal expanded on health IT developers' existing disclosure obligations at § 170.523(k)(1). Those obligations were adopted in the 2014 Edition final rule to promote greater price transparency in certified health IT capabilities required to meet meaningful use objectives and measures; to mitigate confusion in the marketplace; and to reduce the risk that EPs, eligible hospitals, and CAHs would encounter unexpected difficulties in the implementation or use of certified health IT.

As we explained in the Proposed Rule, despite our initial efforts to promote greater transparency and disclosure of information by health IT developers, many providers continue to lack reliable up-front information about health IT products and services. We described reports from providers who have encountered unexpected costs and limitations in connection with their

certified health IT that were not disclosed or contemplated when the technology was initially purchased or licensed. (80 FR 16880–81). We said that the failure of developers to disclose “known material information” about limitations or additional types of costs associated with the capabilities of certified health IT diminishes both the reliability of certified health IT and of certifications issued under the ONC Health IT Certification Program. In particular, the failure of developers to disclose such information creates a substantial risk that existing or prospective users of certified health IT will encounter problems implementing and using the health IT in a manner consistent with its certification. Moreover, inadequate or incomplete information about health IT products and services distorts the marketplace by preventing customers from accurately assessing the costs and capabilities of different technologies and selecting the most appropriate solutions to their needs, which increases the likelihood of downstream implementation problems and, ultimately, reduced opportunities to use health IT to improve health and health care. Finally, customers who purchase or license inappropriate or suboptimal technologies may find it difficult to switch to superior alternatives due to the often significant financial and other “switching costs” associated with health IT.¹⁷⁵ When providers become “locked in” to technologies or solutions that do not meet their needs or the needs of their patients, health IT developers have fewer incentives to innovate and compete on those aspects of health IT that providers and their patients most value and need.

For all of these reasons, we proposed to revise and strengthen our existing transparency and disclosure requirements in three key respects.

First, under our proposal, a health IT developer's obligation to disclose “additional types of costs” would no longer be confined to the use of capabilities to demonstrate a meaningful use objective or measure under the EHR Incentive Programs. Instead, ONC-ACBs would be required to ensure that developers disclose any additional types of costs that a user may incur in order to implement or use capabilities of

¹⁷⁴ In our annual surveillance guidance to ONC-ACBs for the calendar year 2016 surveillance period, we stated that ONC-ACBs should be aware of the proposals in the 2015 Edition proposed rule that could affect their surveillance responsibilities and indicated that we would update our surveillance guidance as necessary in the event that such proposals were finalized. ONC, *ONC Health IT Certification Program, Program Policy Guidance #15-01* (July 16, 2015), http://healthit.gov/sites/default/files/policy/onc-acb_cy16annual_surveillance_guidance.pdf.

¹⁷⁵ The costs of switching to a new technology include not only the costs of purchasing or licensing the technology itself but of installing and integrating it with other administrative and clinical IT systems, migrating data, redesigning associated workflows and processes, and retraining staff to use the new technology. The transition may also disrupt normal health care and business operations, adding additional costs and strain on provider organizations and staff.

certified health IT, whether to demonstrate meaningful use objectives or measures or for any other purpose within the scope of the health IT's certification.

Second, in addition to "additional types of costs," we proposed that health IT developers would be required to disclose other factors that may similarly interfere with a user's ability to successfully implement certified health IT, including information about certain "limitations" associated with its certified health IT. We explained that the failure to disclose information about limitations—including contractual, technical, and other restrictions or policies—associated with certified health IT creates a substantial risk that current or prospective users will encounter problems implementing the health IT in a manner consistent with its certification. Thus the disclosure of this information is no less important than the disclosure of information about additional types of costs.

Third, with regard to both "limitations" and "additional types of costs," we proposed to significantly broaden the types of information and the level of detail that a health IT developer would be required to disclose. In contrast with the price transparency requirements adopted in the 2014 Edition final rule, which required disclosure only of additional types of costs that a user "would pay" to implement certain capabilities, we proposed to require health IT developers to be more proactive in identifying the kinds of limitations and additional types of costs that a user "may" pay or encounter in order to achieve any use of the health IT within the scope of its certification. Specifically, developers would be required to provide, in plain language, a detailed description of any "known material information" about limitations that a purchaser may encounter, and about additional types of costs that a user may be required to pay, in the course of implementing or using the capabilities of health IT to achieve any use within the scope of its certification. We also provided an extensive discussion of the types of information that would be deemed "material" and of the types of information that developers would and would not be required to disclose. Further, we described the manner in which the information would need to be disclosed as well as safeguards to avoid the disclosure of intellectual property and trade secrets.

Finally, in addition to these three aspects, we proposed one additional element designed to complement the disclosure requirements set forth in the

Proposed Rule. We proposed that in addition to requiring health IT developers to disclose known material information about their certified health IT, an ONC-ACB would be required to obtain a public attestation from every health IT developer to which it issues or has issued a certification for any edition of certified health IT. The attestation would take the form of a written "pledge" by the health IT developer to take the additional, voluntarily step of proactively providing information (which it would already be required to disclose via its website and in marketing and other materials) to all current and prospective customers as well as to any other persons who request such information. While adherence to the attestation would be strictly voluntary, we explained that requiring developers to make the attestation could encourage a culture of greater transparency and accountability in the health IT marketplace. For example, health IT purchasers, implementers, and users (and organizations that represent them) would be invited to approach developers directly and request information most relevant to their health IT decisions and needs. The expectation that developers will provide this information in a way that is more meaningful for stakeholders, consistent with the attestation, would create greater competitive incentives for developers to do so. Developers would also receive important feedback about the types of information that stakeholders find important, which would assist developers in meeting their disclosure obligations under the ONC Health IT Certification Program. For example, requests for information about a particular cost or capability may alert the developer to a material limitation or additional type of cost that it is required to disclose.

Comments. Most commenters strongly supported our proposal to require the disclosure of additional information about certified health IT. Many of these commenters agreed with our assessment that providers and other stakeholders often lack reliable information about certified health IT products and services and, as a result, may encounter unexpected costs and limitations that interfere with their ability to successfully implement and use certified health IT capabilities. Several commenters cited examples of providers encountering unexpected fees to license, implement, upgrade, or use health IT; to exchange or export electronic health information stored in certified health IT; or to integrate certified health IT capabilities and data with other

technologies, organizations, and applications. Similarly, commenters cited examples of providers encountering unanticipated contractual, technical, or other limitations on their ability to implement and use certified health IT capabilities in the manner they anticipated when they purchased or licensed the technology. Some commenters stated that small providers are especially vulnerable to these unexpected challenges because they lack the resources and time to study and understand the complexities associated with developer contracts.

Many commenters stated that the proposed transparency and disclosure requirements would help ensure that providers are informed of these and other considerations and enable them both to more reliably estimate the resources needed to successfully implement certified health IT capabilities and to arrive at a realistic expectation of how those capabilities will perform in the field. Commenters also noted that this increased ability of customers to assess and compare certified health IT products and services could reduce the problems of "lock in" and "unfair surprise" described in our proposal and put pressure on developers to compete to innovate and deliver better and more affordable technologies and solutions based on provider and consumer preferences. Commenters also stated that greater transparency in health IT products and services would help to expose and discourage information blocking and other business practices that frustrate interoperability and prevent the effective sharing of electronic health information. A number of commenters cited our discussion of these issues in our recent Report to Congress on Health Information Blocking.¹⁷⁶

Response. We thank commenters for their detailed and thoughtful feedback on this proposal. As that feedback overwhelmingly demonstrates, the lack of transparency and access to reliable information about health IT products and services is a persistent and pervasive problem that undermines the reliability of certifications issued on behalf of ONC and creates substantial risks that users will be unable to successfully implement and derive the benefits of certified health IT. For this and the additional reasons discussed below in our responses to comments on specific aspects of our proposal, we have finalized the transparency and

¹⁷⁶ ONC, *Report to Congress on Health Information Blocking* (April 2015), http://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf (hereinafter "Blocking Report").

disclosure requirements at § 170.523(k). We have finalized these requirements as proposed, except for the attestation requirement, which we have revised. To complement these new requirements, we have also finalized additional reporting requirements to the open data CHPL, which we have added to §§ 170.523(f)(1) and (f)(2). We discuss these revisions below in our response to the comments on this aspect of our proposal.

Comments. Several commenters specifically agreed with our proposal to require health IT developers to disclose known material information about the capabilities of certified health IT, including limitations and additional types of costs. Many commenters also specifically endorsed our proposal to apply these requirements uniformly to all capabilities and uses within the scope of a health IT's certification—not just those required to meet a specific meaningful use objective or measure. Commenters stated that applying clear and uniform standards for the disclosure of this information will be necessary to help customers understand and use an increasing array of certified health IT products, services, and capabilities.

In contrast, some commenters, mostly health IT developers, strongly opposed all of the proposed disclosure requirements. These commenters stated, among other objections, that requiring the disclosure of this information is unnecessary; would be burdensome for developers; and could limit developers' flexibility to design and market their products and services in ways that their customers value. Several commenters stated that the proposed disclosure requirements would be unfair to developers because developers may not be aware of capabilities or uses of their technology that are not specifically required to demonstrate the meaningful use of certified health IT under the EHR Incentive Programs. Some commenters also stated that developers should not be expected to know about—or required to disclose—limitations or additional types of costs that may apply to third-party components or that may flow from local implementation decisions.

Response. While we appreciate the concerns raised by some commenters, we believe they are outweighed by the need to promote greater and more meaningful disclosure of information by developers of health IT certified on behalf of ONC.

First, we respectfully disagree with the assertion that these transparency and disclosure requirements are unnecessary. Our conclusion is based on the overwhelming support for this

proposal from providers and other customers of certified health IT, whose comments and first-hand accounts of the health IT marketplace affirm our assessment in the Proposed Rule. Those comments suggest that many customers lack access to reliable information about certified health IT products and services and, as a result, are more likely to encounter unexpected costs and limitations that interfere with their ability to successfully implement and use certified health IT capabilities. The comments also provide insight into other deleterious consequences that flow from a lack of basic transparency in the marketplace, including the increased risk that developers will engage in information blocking and other business practices that undermine the goals of certification and the ONC Health IT Certification Program.

Second, we disagree that the transparency and disclosure requirements are burdensome or unfair to health IT developers. We note that developers are not required to disclose information of which they are not and could not reasonably be aware, nor to account for every conceivable cost or implementation hurdle that a customer may encounter in order to successfully implement and use the capabilities of a developer's certified health IT. Indeed, we recognized in the Proposed Rule that certified health IT often functions in combination with many third party technologies and services whose specific costs and limitations may be difficult for a health IT developer to precisely predict or ascertain. Local implementation factors and other individual circumstances also vary substantially among customers and impact the cost and complexity of implementing certified health IT. In addition, the costs of upgrading health IT to meet new regulatory requirements or compliance timelines, which are subject to change, may make some particular types of additional costs especially difficult to forecast.

Nevertheless, it is reasonable to assume that health IT developers are experts on their own products and services and possess sophisticated technical and market knowledge related to the implementation and use of health IT in a variety of settings in which their products are used. Through their accumulated experience developing and providing health IT solutions to their customers, health IT developers should be familiar with the types of costs and limitations that most users encounter, and therefore must describe these in sufficient detail so as to provide potential customers with the information they need to make informed

purchasing or licensing and implementation decisions.

Finally, we disagree that the transparency and disclosure requirements will limit developers' flexibility to design and market their products and services in ways that their customers value. To the contrary, greater transparency in health IT developers' business practices will provide customers with the basic information they need to make informed decisions in the marketplace, which will in turn encourage and enable developers to experiment, innovate, and compete to deliver products and services that customers demand and on such prices and terms that meet their individual needs and requirements.

Comments. Several commenters stated that ONC-ACBs and developers may have difficulty complying with the proposed disclosure requirements because we had not specified with sufficient clarity or detail the types of information that developers would be required to disclose. Two ONC-ACBs indicated that additional guidance may be needed to fully implement the requirements. However, another ONC-ACB that commented extensively on the proposal did not raise these concerns. In addition, the ONC-AA supported our approach and noted that the criteria and examples described in the Proposed Rule provided sufficient guidance to ONC-ACBs and developers. The ONC-AA stated that while ONC-ACBs and developers would inevitably need to exercise some degree of judgment regarding the precise form and content of the required disclosures, comparisons across developers' disclosures would promote consistency and provide additional clarity to ONC-ACBs, developers, and other stakeholders as to the types of information and level of detail that must be disclosed.

Response. We understand the desire for clear and predictable rules governing these expanded disclosure requirements under the ONC Health IT Certification Program. We note that our ability to issue guidance is limited by the problem we are trying to solve; that is, the lack of transparency in the marketplace means we lack detailed information about many types of limitations and additional types of costs that customers and users may encounter in the course of implementing and using certified health IT and that developers would be required to disclose.

Nevertheless, based on the comments and in particular the feedback of the ONC-AA, we believe that the principles and examples provided in the Proposed Rule provide a workable starting point for ONC-ACBs to apply, and developers

to comply with, the disclosure requirements. As stated by the ONC-AA, while these principles inevitably involve the exercise of some discretion, comparisons across developers' disclosures over time will provide consistency and additional clarity regarding the types of information and level of detail that developers must disclose. In addition, as our visibility into these practices improves, we stand ready to issue additional guidance.

For the sake of additional clarity, we clarify that to comply with the disclosure requirements, a developer must disclose in plain language—on its website and in all marketing materials, communications statements, and other assertions related to its certified health IT—a detailed description of all known material information concerning limitations and additional types of costs that a person may encounter or incur to implement or use certified health IT capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification. Such information is "material" (and its disclosure therefore required) if the failure to disclose it could substantially interfere with the ability of a user or prospective user to implement certified health IT in a manner consistent with its certification. Certain kinds of limitations and additional types of costs will always be material and thus, if known, must be disclosed. These include but are not limited to:

- Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

- Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified.

- Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any

capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

As already noted, developers are not required to disclose information of which they are not and could not reasonably be aware, nor to account for every conceivable type of cost or implementation hurdle that a customer may encounter in order to successfully implement and use the capabilities of the developer's certified health IT. Developers are required, however, to describe *with particularity* the nature, magnitude, and extent of the limitations or types of costs. A developer's disclosure possesses the requisite particularity if it contains sufficient information and detail from which a reasonable person under the circumstances would, without special effort, be able to reasonably identify the specific limitations he may encounter and reasonably understand the potential costs he may incur in the course of implementing and using capabilities for any purpose within the scope of the health IT's certification.

Comments. A commenter asked whether a developer would be required to disclose known material limitations of its certified health IT where the limitations are due to the actions of a third-party from whom the developer purchases, licenses, or obtains technology, products, or services in connection with its own certified health IT. The commenter noted that in describing certain kinds of presumptively material information that a developer would be required to disclose, we mentioned third parties only in connection with types of costs and not limitations.

Response. We clarify that a developer must disclose known material limitations of its certified health IT, including limitations caused by a third party that the developer should be aware of under the circumstances.

A developer's disclosure obligations are limited to material information that the developer knows or should know about under the circumstances. The reference to third parties at § 170.526(k)(1)(iv)(A) and above is intended to limit the material types of costs a developer will be presumed to know about to those that the developer itself imposes or that are imposed by a third party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT. This reflects the reality that developers are unlikely to know about types of

costs imposed by third parties with whom they do not have a contractual relationship. In contrast, because limitations include not only contractual restrictions but also technical and practical limitations of a developer's technology, developers will often be aware of material limitations notwithstanding the existence of a contractual relationship, and there is therefore no reason to expressly qualify the types of material limitations for which a developer may, in appropriate circumstances, be presumed to have knowledge.

Comments. Several commenters who supported our proposal urged us to require the disclosure of more specific information about prices and cost structures for health IT products and services. Some of these commenters suggested that developers be required to disclose specific prices for each service a user may need and provide guidance on how relevant factors—such as the volume of transmissions, geography, interfaces, and exchange partner technology—may impact the costs of those services. One commenter stated that developers should be required to disclose more detailed and specific cost structures that include costs and fees not covered by the provider's service contract. Another commenter stated that developers should be required to disclose costs that could arise from common end-user customizations and implementations of the developer's health IT. Commenters believed that requiring the disclosure of this information would enable customers to more easily and accurately estimate their likely total cost of ownership and other costs.

In contrast, several health IT developers and a few other commenters strongly objected to a requirement to disclose any additional information about prices or costs. One commenter stated that this information and other "commercial terms and conditions" are too varied and complex to be disclosed in a useful manner to customers. Other commenters worried that requiring disclosure of this information could expose intellectual property, trade secrets, or other sensitive information.

Response. We thank commenters for their extensive input regarding the types of costs and price information health IT developers should be required to disclose.

We understand the importance of ensuring that health IT developers' disclosures provide meaningful information to customers and users of certified health IT. We believe it is important for developers to provide the kind of information and level of detail

that will enable ordinary purchasers, licensees, and users to understand and make informed health IT purchasing and implementation decisions.

At the same time, we appreciate that the disclosure of certain kinds of proprietary or confidential information may not be necessary to achieve these goals and may also lead to undesirable consequences. Requiring developers to disclose trade secrets and other confidential information, for example, could dampen innovation by making it difficult for developers to license and make their technologies available on terms that protect their research and investments.¹⁷⁷ And requiring the disclosure of detailed price information could lessen price competition or even lead to price coordination among competitors, at least for certain kinds of products and services in highly concentrated markets.

We believe the approach described in the Proposed Rule accommodates these concerns by ensuring that developers' disclosures are comprehensive, and thus meaningful, while also providing certain safeguards against the unnecessary disclosure of proprietary or confidential information.

Consistent with that approach, and to comply with this final rule, a developer must make a comprehensive disclosure of all known material information regarding its certified health IT—including limitations and additional types of costs. With respect to types of costs, the disclosure must identify and describe the types of costs *with particularity*, from which a potential customer or user would be able to reasonably understand his potential costs to implement and use the health IT for any purpose within the scope of the health IT's certification. The disclosure must also describe the factors that impact additional types of costs, including but not limited to geographical considerations, volume and usage, costs associated with necessary interfaces or other licenses or technology, and costs associated with exchange partner technology and characteristics, among other relevant factors. Since certified technical capabilities may be bundled with non-certified capabilities, any disclosure would need to include an explanation of any limitations such other non-certified capabilities may have on the use or implementation of the certified capabilities.¹⁷⁸ Developers have

substantial flexibility as to the content of their disclosures, including how they choose to describe the particular limitations and additional types of costs associated with their certified health IT products and services. As such, developers should be able to comply with the disclosure requirements without publishing their prices or cost structures or unnecessarily disclosing information that they deem confidential.

The following scenario and discussion further illustrate these requirements.

• *Scenario:* A Health IT Module is certified to the 2014 Edition transitions of care certification criterion at § 170.314(b)(1). The developer of the Health IT Module charges a yearly "subscription fee" for the use of the capability. In making the capability available, the developer bundles it with its own HISP. Because the developer is not a member of any trust network, users can only exchange transitions of care summaries with other users of the developer's own HISP and with users of third-party HISPs with which the developer has negotiated or is willing to negotiate a trust agreement. The developer also charges a "transaction fee" for each transitions of care summary sent or received via a third-party HISP (the transaction fee does not apply for transitions of care summaries exchanged among users of the developer's own HISP).

Under these facts, the developer must disclose the existence of the subscription fee and the transaction fee—each of which is a known material type of cost associated with the transitions of care capability. In addition, the developer must disclose the known material limitation (and any associated additional types of costs) presented by its HISP policy. The developer must describe each of these additional types of costs and limitations with particularity to the extent they impact the implementation and use of the transitions of care capability for any purpose to which it is certified.

Beginning with the "subscription fee," the developer must disclose that there is such a fee along with any factors that impact the amount a customer would have to pay. Examples include number of licenses or limitations on the number of workstations where the software is deployed, additional types of costs related to the volume of transactions, or usage, or associated bandwidth costs for a customer's transactions. Such factors would need to

be described with particularity. For example, for additional types of costs related to the volume of transactions, the developer would need to explain how the volume of transactions would be measured and if variations in volume or types of transactions may trigger additional fees or variations in the subscription fee.

Turning to the developer's HISP policy, the developer must disclose this material limitation and the additional types of costs a user may incur as a result. The developer must explain, for example, that as a result of its policy the transitions of care capability is restricted and users will be unable to exchange transitions of care summaries with users of third-party HISPs with whom the developer does not have a trust agreement. The developer must describe, in plain terms, its current network of HISPs and how such network would enable a user to exchange transitions of care summaries with users of other HISPs servicing a provider's local referral area, including HISPs that participate in trust networks. Further, the disclosure needs to clearly identify any HISPs with whom the developer will not permit exchange or which the developer knows will not agree to a trust agreement with the developer (e.g., because the developer is not a member of a particular trust network). If the developer offers the option to customers to connect to third-party HISPs with whom the developer currently has no relationship, the developer must describe the process for customers to request such connectivity. The developer must also describe any additional types of costs that may apply for this service, including a description of any factors (e.g., geographical considerations or variability in HISP technologies and trust policies) that impact the amount a customer would have to pay.

Finally, the developer would need to disclose the separate "transaction fee" charged for exchanging transitions of care summaries with users of third-party HISPs. Disclosure of all additional types of costs based on volume, geography, or exchange partner technology would be required. The developer would also be required to provide additional information to assist the customer in realistically understanding additional potential costs of sending and receiving transitions of care summaries via third-party HISPs.

The scenario and discussion above illustrate the substantial flexibility developers have in determining the content of their disclosures, including how they choose to describe the particular limitations and types of costs

¹⁷⁷ See M. Jager, 1 Trade Secrets Law § 1.1; Restatement (Third) of Unfair Competition § 39, cmt. a.

¹⁷⁸ Health IT includes "hardware, software, integrated technologies or related licenses,

intellectual property, upgrades, or packaged solutions sold as services. . . ." 42 U.S.C. § 300j(5).

associated with their certified health IT products and services. We caution, however, that developers are ultimately responsible for effectuating a comprehensive disclosure that satisfies the expanded requirements of this final rule. Because developers have substantial flexibility as to the form and content of their disclosures, it is unlikely that they would have to disclose proprietary or confidential information in order to comply with these requirements. However, the safeguards we have adopted are prophylactic and do not create a substantive basis for a developer to refuse to comply with the requirements. Thus a developer cannot cure a deficient disclosure or avoid a non-conformity finding by asserting that the disclosure of known material limitations or types of costs would require it to disclose trade secrets or other proprietary or confidential information. We note that the ONC Health IT Certification Program is a voluntary program. To the extent that developers choose to seek certification under the Program and to market their products and services as certified health IT, they must comply with the transparency and disclosure requirements in their entirety.

Comments. An ONC-ACB stated that some health IT developers have circumvented the requirement to disclose required information on their websites by omitting discussion of the certification or certified status of their health IT. The ONC-ACB asked us to clarify whether such conduct is permissible or constitutes a violation of the disclosure requirements under § 170.523(k)(1). Relatedly, multiple ONC-ACBs asked whether it would be permissible for a developer to use an abbreviated or alternative disclosure more appropriate to the kind of marketing material and medium at issue. One commenter noted that requiring a detailed disclosure of information in *all* marketing materials or assertions about certified health IT is impracticable and not helpful to customers. It may also discourage developers from including such assertions in marketing and promotional materials or from using certain kinds of materials or media.

Response. A health IT developer's website is not only one of its most powerful marketing tools but also, for most people, among the most readily available sources of information about a developer's health IT products and services. It is therefore essential that a developer include the information specified by § 170.523(k)(1) on its website. This information must be

included and updated on the developer's website regardless of whether the website refers to the certification or certified status of the developer's health IT. The information must also be located in a place that is accessible and obvious to viewers and contextually relevant to the certification criteria to which the disclosures pertain.

For the reasons stated by the commenters, we agree that requiring a comprehensive disclosure in all marketing materials and other assertions may be burdensome and counterproductive to our goal of providing this information to customers in a manner that is meaningful and likely to inform. Therefore, we clarify that a developer may satisfy the requirement to disclose the information required by § 170.523(k)(1) in its marketing materials, communications statements, and other assertions related to a Complete EHR or Health IT Module's certification by providing an abbreviated disclaimer, appropriate to the material and medium, provided the disclaimer is accompanied by a hyperlink to the complete disclosure on the developer's website. Where a hyperlink is not feasible (for example, in non-visual media), the developer may use another appropriate method to direct the recipient of the marketing material, communication, or assertion to the complete disclosure on its website.

Because of the challenges and accommodations described above, and the need to ensure that customers and users are able to easily locate information about certified health IT products and services, we believe that developers' disclosures should be accessible from a single, authoritative source. Thus, we have included a developer's disclosures as part of the information that an ONC-ACB must submit to ONC for inclusion in the open data CHPL. We have revised § 170.523(f)(1) and (f)(2) to reflect this requirement.

In keeping with the goal of making developers' disclosures accessible and useful to customers and other stakeholders, we have also revised § 170.523(k)(1)(ii), which requires developers to include in their disclosures certain types of administrative and programmatic information they are required to report to ONC. While the reporting and availability of this information is important and is still required by § 170.523(f)(1) and (2), requiring developers to insert all of this information in their disclosures could add unnecessary clutter and detract from the overall accessibility and clarity of those disclosures. Therefore, under

§ 170.523(k)(1)(ii), developers must include in their disclosures only a subset of this information that will be valuable to customers in making informed decisions about their certified health IT.

Comments. Several commenters supported our proposal to require developers to attest to voluntarily providing information about their required disclosures to additional persons and in additional circumstances. Other commenters questioned the value of this requirement or stated that it was duplicative of the other requirements we proposed. Some commenters stated that requiring developers to provide such an attestation as a condition of certification would in effect make compliance with the attestation mandatory.

Response. We appreciate the comments in support of the proposed attestation requirement, which we regard as a key feature of the transparency and disclosure requirements adopted in this final rule. In response to the comments questioning the value of this additional requirement, we clarify that the purpose of the attestation is to create market incentives—independent of any regulatory obligations—for health IT developers to be more transparent about their health IT products, services, and business practices. Although the attestation does not create any additional disclosure obligations under the ONC Health IT Certification Program, we believe it will encourage developers to make a good faith effort to ensure that customers and other persons actually receive the information that developers are required to disclose at such times and in such a manner as is likely to be useful in informing their health IT purchasing or licensing, implementation, and other decisions.

In the Proposed Rule, we explained that the attestation would take the form of a written "pledge" by the developer to take the additional, voluntarily step of proactively providing information (which it would already be required to disclose via its Web site and in marketing and other materials) to all current and prospective customers as well as to any other persons who request such information. While we stated that the attestation would not broaden or change a health IT developer's disclosure obligations under the ONC Health IT Certification Program, some commenters believed that in practice developers would be forced to comply with the attestation. Because that was and is not our intent, we have revised the attestation requirement. Under the revised

approach, which we have codified at § 170.523(k)(2), a developer must either attest that it will voluntarily take the actions described above, or, in the alternative, attest that it will not take these actions. Further, an ONC-ACB will be required to include the developer's attestation in the information submitted to the open data CHPL so that persons can easily identify which attestation the developer has made. We have revised §§ 170.523(f)(1) and (f)(2) accordingly.

3. Open Data Certified Health IT Product List (CHPL)

We proposed to require ONC-ACBs to report an expanded set of information to ONC for inclusion in the CHPL upon its conversion from its present form to an open data file represented in both XML and JSON and with accompanying API functionality. We are converting the CHPL to this new "open data CHPL" in response to feedback from stakeholders regarding the accessibility of information on the CHPL, especially the information contained in the publicly available test reports for certified health IT products.¹⁷⁹ We estimated that the conversion along with the future additional data collection we have proposed for 2015 Edition certifications would occur over the next 12 to 18 months from the date the Proposed Rule was issued.

To complement this conversion, we proposed to require ONC-ACBs to report an expanded set of information to ONC for inclusion in the open data CHPL. Specifically, we proposed to revise § 170.523(f) to move the current (f) to (f)(2) and to create a new paragraph (f)(1) that would require

ONC-ACBs upon issuing a 2015 Edition (or any subsequent edition certification) to report on the same data elements they report to ONC under § 170.523(f), the information contained in the publicly available test report, and certain additional data listed in the Proposed Rule. We explained that the additional data reported to the open data CHPL would include the information ONC-ACBs would be required to report in connection with corrective action plans under the proposal "In-the-field Surveillance and Maintenance of Certification" in the Proposed Rule. Because this data would be required for all, and not only 2015 Edition, certified health IT, we also proposed to revise new § 170.523(f)(2) (former § 170.523(f)) accordingly.

Consistent with ONC-ACBs' current reporting practice required by § 170.523(f), ONC-ACBs would be required to submit the additional data no less frequently than weekly. Because this expanded list of data would largely subsume the data included in the test results summary, we would no longer require for 2015 Edition and subsequent edition certifications that ONC-ACBs provide a publicly accessible hyperlink to the test results used to certify a Health IT Module.

In submitting this data related to corrective action and surveillance, ONC-ACBs would be required to exclude any information that would identify any user or location that participated in or was subject to surveillance (as currently required for ONC-ACBs' annual surveillance results reported to the ONC). ONC-ACBs would not be required and should take care not to submit proprietary information to ONC for inclusion in the open data file. With respect to the reporting of corrective action plan and surveillance information for health IT, an ONC-ACB would be able to meet the requirement by summarizing the deficiencies leading to its non-conformity determination without disclosing information that the ONC-ACB believes could be proprietary or expose it to liability.

Consistent with these proposals, we also proposed to make a conforming modification to 45 CFR 170.523(k)(1)(ii) which currently cross references § 170.523(f) to cross reference proposed paragraph (f)(2) for 2014 Edition certifications and an equivalent set of data (minus the test results summary) in paragraph (f)(1) for 2015 Edition and subsequent certifications.

Comments. Most commenters supported requiring ONC-ACBs to report an expanded set of information to ONC for inclusion in the open data

CHPL. Multiple commenters agreed that information contained in the CHPL has previously been difficult to access and use and supported our proposal and plans to make this information easier to access. Commenters stated that this information and the open data CHPL more generally would provide greater product transparency, with a focus on surveillance, user-centered design, and testing results.

Response. We appreciate these comments in support of our proposal. We have finalized this proposal in its entirety, subject to minor clarifications and revisions discussed below.

Comments. Commenters offered suggestions on operational details of the conversion of the current CHPL to an open data format and on how we should subsequently collect and organize information via the open data CHPL.

Response. We appreciate these suggestions. While the conversion of the CHPL is already underway, we will consider these comments on operational aspects of the open data CHPL as we continue to implement these efforts.

Comments. Some commenters stated that this proposal was unnecessary or that its benefits would be outweighed by associated costs and administrative burden of collecting and reporting an expanded set of information to ONC for inclusion in the new open data CHPL. Commenters asked us to review the proposed reporting requirements to see if they might be clarified and simplified.

Response. While we recognize that the collection and reporting of additional data to the open data CHPL will place a new reporting burden on ONC-ACBs, we believe that the benefit to the public of having all of this data about product certification in granular detail far outweighs the administrative burden it will take to report this information.

Comments. A number of commenters, including several health IT developers, objected to the reporting of corrective action plan information to the publicly accessible open data CHPL. Some commenters felt that information about non-conformities should not be made public unless and until the developer of the certified Complete EHR or certified Health IT Module at issue has been given a full and fair opportunity to contest the ONC-ACB's determination, including whether the developer was responsible or "at fault" for the non-conformity. Other commenters stated that such information should never be made public because it is bound to lack important context, could be misinterpreted, or would not offer substantial value to health IT customers and users. Separately, some commenters

¹⁷⁹ As the ONC Health IT Certification Program has matured, ONC-ACBs have continued to report the products and information about the products they have certified to ONC for listing on the CHPL. As part of the 2014 Edition final rule (77 FR 54271), we required additional transparency in the ONC Health IT Certification Program in the form of a hyperlink that ONC-ACBs needed to maintain that would enable the public to access the test results that the ONC-ACB used as the basis for issuing a certification. For all 2014 Edition products certified under the ONC Health IT Certification Program, the test results are available in a standardized summary accessible and from the product's detailed information page on the CHPL Web page. The test result summary includes granular detail from ATLS about the testing performed, including, among other information: The certification criteria tested; the test procedure, test data, and test tool versions used during testing for each certification criterion; instances where optional portions of certification criteria were tested; and which standard was used for testing when a certification criterion allowed for more than one standard to be used to meet the certification criterion. The test result summary also includes the user-centered design information and summative tests results applicable to a product in cases where it was required to meet the "safety-enhanced design" certification criterion (§ 170.314(g)(3)) in order to ultimately be certified.

raised concerns regarding the reporting of proprietary or competitively sensitive information.

Response. We have addressed the concerns related to the submission of corrective action plan and related information to the open data CHPL in section IV.D.1 of this preamble (“‘In-the-field’ Surveillance and Maintenance of Certification Criteria”). For the reasons stated there, we have finalized the requirement to submit a corrective action plan and related information to the open data CHPL. Further, we have revised the specific data elements that must be submitted to accommodate the revised randomized in-the-field surveillance and corrective action plan and related reporting requirements finalized at §§ 170.556(c)–(e).

Comments. Some commenters expressed confusion as to why we proposed to require the submission of corrective action and related information only for randomized surveillance and not for other surveillance activities. Commenters also suggested several technical clarifications to our proposed regulation text to ensure alignment between our “Open Data CHPL” and “‘In-the-field’ Surveillance and Maintenance of Certification” proposals.

Response. We have responded to these concerns in section IV.D.1 of this preamble (“‘In-the-field’ Surveillance and Maintenance of Certification Criteria”) and refer commenters to that section for a more detailed treatment of these issues. For the reasons stated there, we agree with commenters that the requirement to submit corrective action and related information to the open data CHPL should be applied to all forms of surveillance and all confirmed non-conformities. We have also refined the data elements required to be reported for reasons also set forth in section IV.D.1 of this preamble. To implement these changes we have revised the randomized in-the-field surveillance and corrective action plan reporting requirements at §§ 170.556(c)–(e) and have made conforming revisions to § 170.523(k)(1) and § 170.523(k)(2) to accommodate the revised data elements.

As discussed in section IV.D.2 of this preamble (“Transparency and Disclosure Requirements”), we have also added developers’ disclosures required by § 170.523(k)(1) and their attestations required by § 170.523(k)(2) to the data that must be submitted to ONC for inclusion in the open data CHPL.

4. Records Retention

We proposed to change the records retention requirement in § 170.523(g) in

two ways. We proposed to require that ONC–ACBs retain all records related to the certification of Complete EHRs and/or Health IT Module(s) (including EHR Modules) for a minimum of 6 years instead of 5 years as was required by regulation. We stated that this proposal would make certification records available for a longer time period, which may be necessary for HHS programmatic purposes such as evaluations or audits. We also proposed that records of certifications performed under the ONC Health IT Certification Program must be available to HHS upon request during the proposed 6-year period that a record is retained. We stated that this would help clarify the availability of certification records for agencies (e.g., CMS) and authorities (e.g., the Office of Inspector General) within HHS.

Comments. A majority of commenters expressed support for the proposed 6-year records retention requirement without additional comment. One commenter suggested a 10-year requirement. Another commenter recommended record retention requirements for the life of the edition of certification criteria. A commenter requested clarification on the start date of the retention period, asking whether the start date was from the first instance of certification for a product or from the last documented date of an activity related to the certification such as surveillance.

Response. We thank commenters for their feedback. We have adopted a records retention provision that requires ONC–ACBs to retain all records related to the certification of Complete EHRs and/or Health IT Module(s) (including EHR Modules) for the “life of the edition” plus an additional 3 years. We have also adopted our proposal to make these records available to HHS upon request during this period of time for the reasons specified above and in the Proposed Rule. We define the “life of the edition” as beginning with the codification of an edition of certification criteria in regulation and ending when the edition is removed from regulation. This means that certification records for a Complete EHR and/or Health IT Module(s) (including EHR Modules) certified to a specific edition (e.g., the 2015 Edition) must be kept for a minimum of 3 years after the effective date of the removal of that edition from the Code of Federal Regulations (CFR). This approach is responsive to commenters and addresses the goal of ensuring records are available for HHS programs, including evaluations and audits, during a relevant period of time. It provides more clarity and certainty than establishing a term such as 6 or 10

years, which may not be a sufficient period of time or too long a period of time. It also provides consistency and reduced burden for ONC–ACB record keeping. To illustrate this point, establishing a record keeping period based on an event such as an instance of first certification or a surveillance activity would lead to variances in ONC–ACB record keeping for certified health IT, while under our finalized approach all records would be retained until a regulatory certain date (at least 3 years after an edition is removed from the CFR). To note, the record would include all documents related to the issued certification, such as test results and surveillance engagements and results.

5. Complaints Reporting

We proposed that ONC–ACBs provide ONC (the National Coordinator) with a list of complaints received on a quarterly basis. We proposed that ONC–ACB indicate in their submission the number of complaints received, the nature or substance of each complaint, and the type of complainant for each complaint (e.g., type of provider, health IT developer, etc.). We stated that this information would provide further insight into potential concerns with certified health IT and/or the ONC Health IT Certification Program and give ONC a better ability to identify trends or issues that may require action including notification of the public.

Comments. A majority of commenters expressed support for the proposed quarterly complaints reporting requirement. Some commenters, however, expressed opposition or concern with the proposed requirement. These commenters stated that the proposed requirement would add certification cost without value. A few commenters recommended a more robust reporting requirement than proposed, suggesting we require a more comprehensive list of complaint data as well as aggregated and analyzed data. One commenter requested clarification on whether the proposed requirement would apply to any complaint received by an ONC–ACB, such as complaints about an ONC–ACB’s services and complaints about certified Health IT Modules.

Response. We have adopted this requirement as proposed with clarifications in response to comments. We continue to believe that this requirement will provide us with insight and situational awareness of issues related to the ONC Health IT Certification Program. We further believe these benefits outweigh the limited reporting burden we have

specified, which does *not* adopt any new reporting requirements as suggested by a few commenters. We clarify that this requirement applies to all complaints received by the ONC-ACB. This includes, but is not limited to, complaints regarding ONC-ACB services, certified health IT, and the ONC Health IT Certification Program in general. To provide ONC-ACBs sufficient time to meet this new requirement, this provision will become effective on April 1, 2016. This means that we expect ONC-ACBs to first provide ONC with a list of complaints received on July 1, 2016.

We intend to provide, as necessary, more specific guidance to ONC-ACBs through the annual ONC Health IT Certification Program surveillance guidance on reporting complaints received regarding certified Health IT Modules.

6. Adaptations and Updates of Certified Health IT

We proposed to require that ONC-ACBs obtain monthly reports from health IT developers regarding their certified health IT. Specifically, we proposed to require that ONC-ACBs obtain a record of all adaptations and updates, including changes to user-facing aspects, made to certified health IT (*i.e.*, Complete EHRs and certified Health IT Modules), on a monthly basis each calendar year, and we requested comment on whether we should require even more frequent reporting. We stated that this new PoPC would apply for all certified Complete EHRs and certified Health IT Modules (which includes “EHR Modules”) to the 2014 Edition and all certified Health IT Modules to the 2015 Edition.

We proposed that the PoPC would become effective with this final rule and we would expect ONC-ACBs to begin complying with the PoPC at the beginning of the first full calendar month that is at least 30 days after the effective date of the final rule. We explained that we would not expect the information in these records to be reported to ONC and listed on the CHPL. Rather, we stated that the best course of action would be for ONC-ACBs to retain this information to provide awareness to the ONC-ACB on adaptations and updates made to technologies they certified.

Comments. We received mixed comments in response to the proposal. A number of commenters supported the proposal, but expressed concerns with the volume and frequency of updates to certified health IT. Commenters stated that updates could arise from relatively small changes to software code that do

not result in risks to the certified health IT and that the burden to collect a list of these updates would not be worth the effort. Some commenters noted that health IT developers time their major updates with certification to reflect a new product listing on the CHPL whereas others do not. These commenters suggested there is inconsistency in the industry in the versioning of certified products. One commenter recommended that we provide guidance on consistently distinguishing major from minor updates for products listed on the CHPL.

Response. In response to comments and to balance the ONC-ACBs’ burden, we have adopted a more limited requirement than proposed. We agree with commenters that many updates to certified health IT products would not normally pose a risk to certified capabilities or patient safety. As such, we have limited the requirement to only adaptations (all adaptations); and all updates that affect the capabilities included in certification criteria to which the “safety-enhanced design” certification criteria apply.¹⁸⁰ These types of updates, particularly changes to the user-interface, pose the greatest risk to patient safety. The adoption of this requirement will provide ONC-ACBs with more insight and transparency into these kinds of updates and adaptations, which should improve ONC-ACBs’ situational awareness and surveillance.

We thank the commenter for the feedback on distinguishing major and minor updates. We first note that, as stated in the 2014 Edition final rule (77 FR 54268), unless adaptations are presented for separate certification, the CHPL would not independently list the adaptation because it is considered part of a previously certified Complete EHR

¹⁸⁰ 2014 Edition certification criteria: CPOE (§ 170.314(a)(1)); drug-drug, drug-allergy interaction checks (§ 170.314(a)(2)); medication list (§ 170.314(a)(6)); medication allergy list (§ 170.314(a)(7)); clinical decision support (§ 170.314(a)(8)); electronic medication administration record (§ 170.314(a)(16)); CPOE—medications (§ 170.314(a)(18)); CPOE—laboratory (§ 170.314(a)(19)); CPOE—diagnostic imaging (§ 170.314(a)(20)); electronic prescribing (§ 170.314(b)(3)); clinical information reconciliation (§ 170.314(b)(4)); and clinical information reconciliation and incorporation (§ 170.314(b)(9)).

2015 Edition certification criteria: CPOE—medications (§ 170.315(a)(1)); CPOE—laboratory (§ 170.315(a)(2)); CPOE—diagnostic imaging (§ 170.315(a)(3)); drug-drug, drug allergy interaction checks (§ 170.315(a)(4)); demographics (§ 170.315(a)(5)); problem list (§ 170.315(a)(6)); medication list (§ 170.315(a)(7)); medication allergy list (§ 170.315(a)(8)); clinical decision support (§ 170.315(a)(9)); implantable device list (§ 170.315(a)(14)); clinical information reconciliation and incorporation (§ 170.315(b)(2)); and electronic prescribing (§ 170.315(b)(3)).

or certified Health IT Module, including EHR Modules. Second, the CHPL does not list updates to products unless they are presented for separate certification. This policy allows a health IT developer to update a product for routine maintenance or to include new or modified capabilities without the need for recertification. However, in these instances, the product name and version on the CHPL would remain unchanged. We established an attestation process for a product to be approved for inherited certified status to provide a more efficient pathway for certification for a new version of a previously certified product in the Permanent Certification Program final rule (76 FR 1306). As part of this policy, we noted that we do not presume the version numbering schema that a health IT developer may choose to utilize. For compliance with this requirement, the focus on “updates” is for *all* updates to certified Health IT that affect the capabilities included in certification criteria to which the “safety-enhanced design” criteria apply.

Comments. A commenter requested that we clarify the definition of an “adaptation.” Another commenter suggested that ONC-ACBs should only be required to monitor adaptations made by the health IT developer as it would be impractical for an ONC-ACB to monitor all customer-initiated adaptations. A commenter requested clarification as to whether an ONC-ACB is expected to review each report from a health IT developer, which the commenter contended could be time-consuming and costly. Another commenter requested clarification as to whether an ONC-ACB has the authorization to suspend or withdraw a certification if the health IT developer does not provide a report of adaptations and updates within the specified timeframe.

Response. We maintain our previously adopted definition of an “adaptation” as a software application designed to run on a different medium that includes the full and exact same capabilities included in the Complete EHR or certified Health IT Module, including EHR Modules (77 FR 54267). We refer readers to the discussion in the 2014 Edition final rule preamble for more detailed examples of adaptations (77 FR 54267). We also previously stated in the 2014 Edition final rule (77 FR 54268) that a health IT developer can choose to seek certification for adaptations which would lead to it being separately listed on the CHPL and permit the health IT developer to openly sell the adaptation to all potential purchasers as a separate certified product.

We would expect that ONC-ACBs obtain a record of adaptations of certified health IT made by the health IT developer as those are the adaptations covered by the issued certification. An ONC-ACB has the discretion in determining how much time and resources should be devoted to reviewing the lists provided by health IT developers. As previously noted, we expect this information to inform ONC-ACBs surveillance activities for certified health IT. In terms of non-compliance by a health IT developer in providing the requisite list, we note that an ONC-ACB retains its authority and oversight over the certifications it issues and has the discretion to implement that authority and oversight in a manner that supports its role and responsibilities as well as the integrity of the ONC Health IT Certification Program.

Comments. We received a number of comments on the proposed frequency in which an ONC-ACB would have to obtain a record of all adaptations and applicable updates, with many commenters suggesting quarterly reporting. Another commenter suggested that the reports should be required only when adaptations and updates occur, or alternately weekly.

Response. We have finalized a calendar quarter reporting frequency for this requirement. This approach addresses commenters' concerns about burden, but also ensures that ONC-ACBs receive timely notifications about new adaptations and updates that could affect the safety of certified health IT. In order to provide ONC-ACBs and health IT developers sufficient time to plan and implement this new requirement, this PoPC will not become effective until April 1, 2016. For clarity, we reiterate that this PoPC applies to all certifications issued to the 2014 Edition, 2015 Edition, and future editions of certification criteria. We expect all ONC-ACBs to receive lists from health IT developers on July 1, 2016, and then every calendar quarter thereafter (e.g., October 1, 2016, January 1, 2017, and so on).

E. "Decertification" of Health IT—Request for Comments

The Proposed Rule proposed and the final rule take certain steps to support the certification of health IT that meets relevant program standards and permits the unrestricted use of certified capabilities that facilitate health information exchange (see the "In-The-Field Surveillance and Maintenance of Certification" and "Transparency and Disclosure Requirements" proposals in section IV.D of this preamble).

In the Proposed Rule, we stated that additional rulemaking would be necessary to implement any approach that would include ONC appropriating an ONC-ACB's delegated authority to issue and terminate a certification, including establishing new program requirements and processes by which ONC or an ONC-ACB would have the grounds to terminate an issued certification. We requested comment on the circumstances, due process, remedies, and other factors that we should consider regarding the termination of a certification. To assist commenters, we provided a brief background of the ONC Health IT Certification Program and examples of the complexities and potential impacts associated with terminating a certification. We asked commenters to account for the potentially profound asymmetric impacts revoking a certification could create, especially if based on the business practices (by health IT developers or their customers) associated with the health IT's use and not necessarily the health IT's performance according to certification requirements.

Comments. Commenters overwhelmingly expressed support for the decertification of health IT products that did not continue to meet certification requirements or proactively blocked the sharing of health information. Of these commenters, the majority supported a clear and structured approach to "decertification," with some commenters specifically recommending a regulatory approach that could be implemented as soon as possible. However, other commenters opposed changing the current approach or, at a minimum, urged caution in implementing a new "decertification" process. In this regard, commenters recommended clear parameters be established that would lead to decertification; appropriate due processes, including sufficient opportunities to correct deficiencies and non-compliance; and safeguards for non-culpable parties, such as "hold harmless" provisions, hardship exemptions, and "safe harbors" when applicable. A few commenters also suggested that further stakeholder input was needed before considering regulations, particularly to fully understand the "downstream" implications of "decertification."

Response. We thank commenters for their feedback. As noted in the Proposed Rule, additional rulemaking would be necessary to implement any new "decertification" process. We will take the comments received under

consideration as we determine whether a new regulatory "decertification" process for health IT is necessary or whether other steps could better support the continued compliance of certified health IT with certification requirements, the unencumbered access and use of certified capabilities of health IT, the unrestricted exchange of health information, and overall interoperability.

V. Incorporation by Reference

- The Office of the Federal Register has established new requirements for materials (e.g., standards and implementation specifications) that agencies incorporate by reference in the **Federal Register** (79 FR 66267; 1 CFR 51.5). Specifically, § 51.5(b) requires agencies to discuss, in the preamble of a final rule, the ways that the materials they incorporate by reference are reasonably available to interested parties and how interested parties can obtain the materials; and summarize, in the preamble of the final rule, the material they incorporate by reference.

To make the materials we have incorporated by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URL provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In certain instances, where noted, access requires a fee or paid membership.

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-119¹⁸¹ require the use of, 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

¹⁸¹ http://www.whitehouse.gov/omb/circulars_a119.

impractical. As discussed in section III.A.2 of this preamble, we have followed the NTTAA and OMB Circular A-119 in adopting standards and implementation specifications, including describing any exceptions in the adoption of standards and implementation specifications. Over the years of adopting standards and implementation specifications for certification, we have worked with SDOs, such as HL7, to make the standards we adopt and incorporate by reference in the **Federal Register** available to interested stakeholders. As described above, this includes making the standards and implementation specifications available through no-cost memberships and no-cost subscriptions.

As required by § 51.5(b), we provide summaries of the standards and implementation specifications we have adopted and incorporated by reference in the **Federal Register**. We also provide relevant information about these standards and implementation specifications throughout section III.3 of the preamble. In particular, in relevant instances, we identify differences between previously adopted versions of standards and implementation specifications and 2015 Edition adopted versions of standards and implementation specifications.

We have organized the following standards and implementation specifications that we have adopted through this final rule according to the sections of the Code of Federal Regulation (CFR) in which they are codified and cross-referenced for associated certification criteria that we have adopted in 45 CFR 170.315.

Transport and Other Protocol Standards—45 CFR 170.202

- *Applicability Statement for Secure Health Transport, Version 1.2.*

URL: <http://wiki.directproject.org/file/view/Applicability+Statement+for+Secure+Health+Transport+v1.2.pdf>. This is a direct access link.

Summary: This document is intended as an applicability statement providing constrained conformance guidance on the interoperable use of a set of Requests for Comments (RFCs) describing methods for achieving security, privacy, data integrity, authentication of sender and receiver, and confirmation of delivery consistent with the data transport needs for health information exchange.

- *Implementation Guide for Delivery Notification in Direct, Version 1.0.*

URL: <http://wiki.directproject.org/file/view/Implementation+Guide+for+Delivery+Notification+in+Direct+v1.0.pdf>. This is a direct access link.

Summary: This document provides implementation guidance enabling Security/Trust Agents (STAs) to provide a high level of assurance that a message has arrived at its destination. It also outlines the various exception flows that result in a compromised message delivery and the mitigation actions that should be taken by STAs to provide success and failure notifications to the sending system.

Functional Standards—45 CFR 170.204

- *HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application (“Infobutton”), Knowledge Request, Release 2.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=208. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Context-aware knowledge retrieval specifications (Infobutton) provide a standard mechanism for clinical information systems to request context-specific clinical knowledge from online resources. Based on the clinical context, which includes characteristics of the patient, provider, care setting, and clinical task, Infobutton(s) anticipates clinicians’ and patients’ questions and provides automated links to resources that may answer those questions.

- *HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: Context-aware knowledge retrieval (Infobutton) into clinical information systems help deliver clinical knowledge to the point of care as well as patient-tailored education material. This specification enables the implementation of context-aware knowledge retrieval applications through a Service Oriented Architecture based on the RESTful software architectural style.

- *HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: Context-aware knowledge retrieval (Infobutton) in clinical

information systems help deliver clinical knowledge to the point of care as well as patient-tailored education material. This implementation guide provides a standard mechanism for EHR systems to submit knowledge requests over the HTTP protocol through a standard using a URL format.

Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information—45 CFR 170.205

- *HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, Draft Standard for Trial Use (DSTU) Release 3 (US Realm), Volumes 1 (Introductory Material) and 2 (Templates and Supporting Material).*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Quality Reporting Document Architecture (QRDA) is an electronic document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data. The Release 3 IG is consistent with the CDA, and Category I is an individual-patient-level quality report. The Release 3 IG includes updates to align with the Quality Data Model version 4.1.2; incorporates appropriate QRDA Category I Release 2 (R2) DSTU comments that were considered as New Feature Requests; and updates of the QRDA I R1 DSTU Release 3 templates to align with the CDA R2 templates where applicable.

- *Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement. The DSTU package must be downloaded in order to access the errata.

Summary: The September 2014 Errata reflects updates for the implementation of QRDA Category I consistent with the Quality Data Model-based Health Quality Measures Format Release 2.1, an incremental version of harmonized clinical quality measure and CDS standards.

- *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use,*

Release 2.1, Volumes 1 (Introductory Material) and 2 (Templates and Supporting Material).

URL: http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_CCDA_CLINNOTES_R1_DSTUR2.1_2015AUG.zip. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Consolidated CDA (C-CDA) IG contains a library of CDA templates, incorporating and harmonizing previous efforts from HL7, IHE, and the Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). The C-CDA Release 2.1 IG, in conjunction with the HL7 CDA Release 2 (CDA R2) standard, is to be used for implementing the following CDA documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care, Consultation Note, CCD, Diagnostic Imaging Reports, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document, and Patient Generated Document (US Realm Header). The Consolidated CDA (C-CDA) Release 2.1 IG provides compatibility between Releases 2.0 and 1.1 by applying industry agreed-upon compatibility principles.

- *HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, Part 1: CDA R2 and Privacy Metadata Reusable Content Profile.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: This guide supports segmenting clinical records so that protected health information (PHI) can be appropriately shared as may be permitted by privacy policies or regulations.

- *HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5.*

URL: <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>. This is a direct access link.

Summary: This document represents the collaborative effort of the American Immunization Registry Association and CDC to improve inter-system communication of immunization records. The guide is intended to

facilitate exchange of immunization records between different systems.

- *HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015.*

URL: <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html>.

Summary: This addendum consolidates the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 information that clarifies the conformance requirements. This supplement does not specify additional requirements; it just clarifies existing ones. Value set requirements, general clarifications, and Immunization IG errata are also provided in this addendum.

- *PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Settings, Release 2.0, April 21, 2015.*

URL: http://www.cdc.gov/nssp/documents/guides/syndrsurvmsgguide2_messagingguide_phn.pdf. This is a direct access link.

Summary: This document represents the collaborative effort of the International Society for Disease Surveillance, CDC, and NIST to specify a national electronic messaging standard that enables disparate health care applications to submit or transmit administrative and clinical data for public health surveillance and response. The scope of the guide is to provide guidelines for sending HL7 v.2.5.1 compliant messages from emergency department, urgent and ambulatory care, and inpatient settings to public health authorities.

- *Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings.*

URL: <http://www.cdc.gov/nssp/documents/guides/erratum-to-the-cdc-phin-2.0-implementation-guide-august-2015.pdf>. This is a direct access link.

Summary: This document contains erratum and conformance clarifications for the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Setting, Release 2.0. Value set requirements and errata are also provided in the addendum.

- *HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, DSTU Release 1.1, Volumes 1*

(Introductory Material) and 2 (Templates and Supporting Material).

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=398. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: As ambulatory health care providers adopt modern EHR systems, the opportunity to automate cancer registry reporting from ambulatory health care provider settings is also increasing and becoming more feasible. This document provides clear and concise specifications for electronic reporting form ambulatory health care provider EHR systems to public health central cancer registries using the HL7 CDA based standards. This document is designed to guide EHR vendors and public health central cancer registries in the implementation of standardized electronic reporting.

- *IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b).*

URL: http://www.ihe.net/TechnicalFramework/upload/IHE_ITI_TF_Rev7-0_Vol2b_FT_2010-08-10.pdf. This is a direct access link.

Summary: This document defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support ongoing patient care. The IHE IT Infrastructure Technical Framework identifies a subset of functional components of the health care enterprise, called “IHE actors,” and specified their interactions in terms of a set of coordinated, standards-based transactions. Volume 2b corresponds to transactions [ITI-29] through [ITI-57].

- *HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=20. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: This document specifies a standard for electronic submission of health care associated infection reports (HAI) to the National Healthcare Safety Network of the CDC. This document defines the overall approach and method of electronic submission and develops constraints defining specific HAI report types.

- *HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volumes 1 (Introductory Material) and 2 (Templates and Supporting Material), December 2014.*

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=385. Access requires a “user account” and license agreement. There is no monetary cost for a user account and license agreement.

Summary: The HL7 Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1—US Realm provides a standardized format for implementers to submit data to fulfill requirements of the Centers for Disease Control and Prevention/ National Center for Health Statistics/ National Health Care Surveys. This IG supports automatic extraction of the data from a provider’s EHR system or data repository. The data are collected through three surveys of ambulatory care services in the United States: The National Ambulatory Medical Care Survey with information from physicians and two national hospital care surveys: the National Hospital Ambulatory Medical Care Surveys and the National Hospital Care Survey with data from hospital emergency and outpatient departments.

Vocabulary Standards for Representing Electronic Health Information—45 CFR 170.207

- *IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.*

URL: http://www.nlm.nih.gov/research/umls/Snomed/us_edition.html. Access requires a user account and license agreement. There is no monetary cost for a user account and license agreement.

Summary: Systemized Nomenclature of Medicine—Clinical Terms (SNOMED CT®) is a comprehensive clinical terminology, originally created by the College of American Pathologists and, as of April 2007, owned, maintained, and distributed by the International Health Terminology Standards Development Organisation. SNOMED CT® improves the recording of information in an EHR system and facilitates better communication, leading to improvements in the quality of care.

- *Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.*

URL: <http://loinc.org/downloads>. Access requires registration, a user account, and license agreement. There is no monetary cost for registration, a user account, and license agreement.

Summary: LOINC® was initiated in 1994 by the Regenstrief Institute and developed by Regenstrief and the LOINC® committee as a response to the demand for electronic movement of

clinical data from laboratories that produce the data to hospitals, provider’s offices, and payers who use the data for clinical care and management purposes. The scope of the LOINC® effort includes laboratory and other clinical observations. The LOINC® database facilitates the exchange and pooling of results for clinical care, outcomes management, and research.

- *RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.*

URL: <http://www.nlm.nih.gov/research/umls/rxnorm/docs/rxnormfiles.html>. Access requires a user account and license agreement. There is no monetary cost for a user account and license agreement.

Summary: RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between vocabularies commonly used in pharmacy management and drug interaction software, RxNorm can mediate messages between systems not using the same software and vocabulary. RxNorm now includes the National Drug File—Reference Terminology (NDF-RT) from the Veterans Health Administration, which is used to code clinical drug properties, including mechanism of action, physiologic effect, and therapeutic category.

- *HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015.*

URL: <http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>. This is a direct access link.

Summary: CDC’s National Center of Immunization and Respiratory Diseases developed and maintains HL7 Table 0292, Vaccine Administered (CVX). CVX includes both active and inactive vaccines available in the U.S. CVX codes for inactive vaccines allow transmission of historical immunization records; when paired with a manufacturer (MVX) code, the specific trade named vaccine may be indicated.

- *National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015.*

URL: http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp. This is a direct access link.

Summary: The Drug Listing Act of 1972 requires registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it by commercial distribution. Drug products are

identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which services as the universal product identifier for drugs. This standard is limited to the NDC vaccine codes identified by CDC at the URL provided.

- *CDC Race and Ethnicity Code Set Version 1.0.*

URL: <http://www.cdc.gov/phin/resources/vocabulary/index.html>. The code set can be accessed through this link.

Summary: The CDC has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards.

- *Request for Comments (RFC) 5646, “Tags for Identifying Languages.”*

URL: <http://www.rfc-editor.org/info/rfc5646>. This is a direct access link.

Summary: RFC 5646 describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object. It also describes how to register values for use in language tags and the creation of user-defined extensions for private interchange.

- *International Telecommunication Union E.123: Notation for national and international telephone numbers, email addresses and Web addresses.*

URL: <http://www.itu.int/rec/T-REC-E.123-200102-I/e>. This is a direct access link.

Summary: This standard applies specifically to the printing of national and international telephone numbers, electronic mail addresses and Web addresses on letterheads, business cards, bills, etc. Regard has been given to the printing of existing telephone directories. The standard notation for printing telephone numbers, Email addresses and Web addresses helps to reduce difficulties and errors, since this address information must be entered exactly to be effective.

- *International Telecommunication Union E.164: The international public telecommunication numbering plan.*

URL: <http://www.itu.int/rec/T-REC-E.164-201011-I/en>. This is a direct access link.

Summary: Recommendation ITU-T E.164 provides the number structure and functionality for the five categories of numbers used for international public telecommunication: Geographic areas, global services, Networks, groups of countries (GoC) and resources for trials. For each of the categories, it details the components of the numbering structure and the digit analysis required to successfully route the calls.

- *Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy (updated April 2, 2015).*

URL: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf>. This is a direct access link.

Summary: This crosswalk links the types of providers and suppliers who are eligible to apply for enrollment in the Medicare program with the appropriate Healthcare Provider Taxonomy Codes. This crosswalk includes the Medicare Specialty Codes for those provider/supplier types who have Medicare Specialty Codes. The Healthcare Provider Taxonomy Code Set is available from the Washington Publishing Company (www.wpc-edi.com) and is maintained by the National Uniform Claim Committee (www.nucc.org).

- *Public Health Data Standards Consortium Source of Payment Typology Code Set, Version 5.0.*

URL: <http://www.phdsc.org/standards/pdfs/SourceofPaymentTypologyVersion5.0.pdf>. This is a direct access link.

Summary: The Source of Payment Typology was developed to create a standard for reporting payer type data that will enhance the payer data classification; it is also intended for use by those collecting data, or analyzing healthcare claims information. The Payment Typology can be used by any analyst who wishes to code source of payment data, including analysts who code administrative or claims data, survey data, clinical trials data, or any other dataset containing this type of data element.

- *The Unified Code of Units of Measure, Revision 1.9.*

URL: <http://unitsofmeasure.org/trac/>. This is a direct access link. The codes can be viewed in html or xml.

Summary: The Unified Code of Units of Measure is a code system intended to include all units of measures being

contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with units.

- *HL7 Version 3 (V3) Normative Edition, 2015, Administrative Gender Value Set and NullFlavor.*

URL: http://www.hl7.org/documentcenter/public_temp_369DCAB9-1C23-BA17-0CAF31D63E2D1A3E/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vs_AdministrativeGender.html; and http://www.hl7.org/documentcenter/public_temp_369DCAB9-1C23-BA17-0CAF31D63E2D1A3E/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vs_NullFlavor.html. These are direct access links. Compliance with a license agreement is required.

Summary: These HL7 Version 3 (V3) Standard Value Sets for administrative gender and NullFlavor provide means for coding birth sex and null flavors.

Standards for Health Information Technology to Protect Electronic Health Information Created, Maintained, and Exchanged—45 CFR 170.210

- *Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014.*

URL: <http://csrc.nist.gov/publications/fips/fips140-2/fips1402annexa.pdf>. This is a direct access link.

Summary: Federal Information Processing Standards Publication (FIPS PUB) 140-2, *Security Requirements for Cryptographic Modules*, specifies the security requirements that are to be satisfied by the cryptographic module utilized within a security system protecting sensitive information within computer and telecommunications systems. The standard provides four increasing qualitative levels of security that are intended to cover the wide range of potential applications and environments in which cryptographic modules may be employed.

- *FIPS PUB 180-4, Secure Hash Standard, 180-4 (August 2015).*

URL: <http://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.180-4.pdf>. This is a direct access link.

Summary: This standard specifies secure hash algorithms—SHA-1, SHA-224, SHA-256, SHA-384, SHA-512, SHA-512/224 and SHA-512/256—for computing a condensed representation of electronic data (message). Secure

hash algorithms are typically used with other cryptographic algorithms, such as digital signature algorithms and keyed-hash message authentication codes, or in the generation of random numbers (bits).

- *ASTM E2147-01 (Reapproved 2013) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved March 1, 2013.*

URL: <http://www.astm.org/Standards/E2147.htm>. This is a direct access link. However, a fee is required to obtain a copy of the standard.

Summary: This specification describes the security requirements involved in the development and implementation of audit and disclosure logs used in health information systems. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems, and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of confidential health care information to external users for use in manual and computer systems. This specification provides for two main purposes, namely: To define the nature, role, and function of system access audit logs and their use in health information systems as a technical and procedural tool to help provide security oversight; and to identify principles for establishing a permanent record of disclosure of health information to external users and the data to be recorded in maintaining it.

VI. Collection of Information Requirements

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

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We sought comment on proposed PRA requirements in the Proposed Rule (80 FR 16893–16895).

Abstract

Under the ONC Health IT Certification Program, accreditation organizations that wish to become the ONC-Approved Accreditor (ONC-AA) must submit certain information, organizations that wish to become an ONC-ACB must submit the information specified by the application requirements, and ONC-ACBs must comply with collection and reporting requirements, records retention requirements, and submit annual surveillance plans and annually report surveillance results.

In the Permanent Certification Program final rule (76 FR 1312–14), we solicited public comment on each of the information collections associated with the requirements described above (and included in regulation at 45 CFR 170.503(b), 170.520, and 170.523(f), (g), and (i), respectively). In the 2014 Edition final rule (77 FR 54275–76), we sought comment on these collection requirements again and finalized an additional requirement at § 170.523(f)(8) for ONC-ACBs to report to ONC a hyperlink with each EHR technology they certify that provides the public with the ability to access the test results used to certify the EHR technology. These collections of information were approved under OMB control number 0955–0013 (previous OMB control number 0990–0378).

In the Proposed Rule, we estimated less than 10 annual respondents for all of the regulatory “collection of information” requirements under Part 170 of Title 45, including those previously approved by OMB and proposed in the Proposed Rule (80 FR 16894). The “collection of information” requirements that apply to the ONC-Approved Accreditor (ONC-AA) are found in § 170.503(b). The “collection of information” requirements that apply to the ONC-ACBs are found in § 170.520; § 170.523(f)(1) and (2), (g), (i), and (o); and § 170.540(c). As stated in the Proposed Rule, we estimated the number of respondents for § 170.503(b) (applicants for ONC-AA status) at two based on past selection processes for the ONC-AA, which have included no more than two applicants. As also stated in the Proposed Rule, we anticipate that there will be three ONC-ACBs

participating in the ONC Health IT Certification Program as this is the current number of ONC-ACBs. Further, since the establishment of the ONC Health IT Certification Program in 2010, ONC has never had more than six applicants for ONC-ACB or ONC-ATCB status or selected more than six ONC-ACBs or ONC-ATCBs.¹⁸²

We concluded that the regulatory “collection of information” requirements under the ONC Health IT Certification Program described above are not subject to the PRA under 5 CFR 1320.3(c). We welcomed comments on this conclusion and the supporting rationale on which it was based.

Comments. We received one comment suggesting that the time we estimated for proposed ONC-ACB surveillance activities may be underestimated in terms of reviewing surveillance guidance, developing plans, and finalizing surveillance results for submission.

Response. We agree with the commenter that our time estimate for surveillance-related activities was an underestimation. We have provided a new estimate as part of the regulatory impact statement.

We continue to estimate fewer than 10 respondents for all of the regulatory “collection of information” requirements under Part 170 of Title 45. Accordingly, the “collection of information” requirements/burden that are associated with this final rule are not subject to the PRA under 5 CFR 1320.3(c).

VII. Regulatory Impact Statement

A. Statement of Need

This final rule is being published to adopt the 2015 Edition. Certification criteria and associated standards and implementation specifications would be used to test and certify health IT in order to make it possible for EPs, eligible hospitals, and CAHs to adopt and implement health IT that can be used to meet the CEHRT definition. EPs, eligible hospitals, and CAHs who participate in the EHR Incentive Programs are required by statute to use CEHRT.¹⁸³

The certification criteria and associated standards and implementation specifications would also support the certification of more types of health IT and health IT that supports care and practice settings

¹⁸² See also: <http://www.healthit.gov/policy-researchers-implementers/authorized-testing-and-certifications-bodies> and <http://www.healthit.gov/policy-researchers-implementers/certification-bodies-testing-laboratories>.

¹⁸³ Section 1848(o) of the Social Security Act.

beyond the scope of the EHR Incentive Programs.

The adoption and implementation of health IT certified to the 2015 Edition promotes interoperability in support of a nationwide health information infrastructure and improves health care quality, safety and efficiency consistent with the goals of the HITECH Act.

B. Overall Impact

We have examined the impact of this final 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). OMB has determined that this final rule is an economically significant rule as we have estimated the costs to develop and prepare health IT to be tested and certified may be greater than \$100 million per year.

a. Costs

This final rule adopts standards, implementation specifications, and certification criteria that establish the capabilities that health IT would need to demonstrate to be certified to the 2015 Edition. Our analysis focuses on the direct effects of the provisions of this final rule—the costs incurred by health IT developers to develop and prepare health IT 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 health IT already certified to the 2014 Edition to upgrade to the proposed 2015 Edition and for, in limited cases, developing and preparing a new Health IT Module to meet the 2015 Edition. The costs for

the testing and certification of health IT 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 (VIII.B.1.a.iii “Testing and Certification Costs for the 2015 Edition”). In this final rule, we have also included estimated costs for complying with new and revised Principles of Proper Conduct for ONC-ACBs.

Because the costs that EPs, eligible hospitals, and CAHs would incur in adopting and implementing (including training, maintenance, and any other ongoing costs) health IT certified to the 2015 Edition is overwhelmingly attributable to the EHR Incentive Programs Stage 3 and Modifications final rule (published elsewhere in this issue of the **Federal Register**), and would not be incurred in the absence of such rulemaking, such costs are not within the scope of the analysis of this final rule; similarly, any benefits that are contingent upon adoption and implementation would be attributable to CMS’s rulemaking.¹⁸⁴ We also note that this final rule does not impose the costs cited as compliance costs, but rather as investments which health IT developers voluntarily take on and may expect to recover with an appropriate rate of return.

i. Development and Preparation Costs for the 2015 Edition

The development and preparation costs we estimate are derived through a health IT developer per criterion cost. In simple terms, we estimate: (1) How many health developers will prepare and develop products against the certification criteria; (2) how many products they will develop; and (3) what it will likely cost them to develop and prepare those products to meet the certification criteria.

Comments. Several commenters expressed concern with the estimated costs and developer hours in the Proposed Rule, stating they were

¹⁸⁴ ONC administers a voluntary certification program that provides no incentives for certification. Therefore, to the extent that providers’ implementation and adoption costs are attributable to CMS’s rulemaking, health IT developers’ preparation and development costs would also be attributable to that rulemaking (because all of the costly activities are, directly or indirectly, incentivized by CMS’s payment structure). However, a professional organization or other such entity could also require or promote certification, thus generating costs and benefits that are attributable to this final rule. To avoid giving the misleading impression that such effects equal zero, we present in this RIA a subset of the relevant impacts—a quantification of costs that are incurred by health IT developers and a qualitative discussion of benefits. (The missing portion of the subset is providers’ implementation and adoption costs).

significantly underestimated. However, one commenter stated the average cost estimate for patient health information capture was significantly overestimated. One commenter stated that the developer hour estimates do not appear to be derived from data reported by health IT developers or consulting companies and recommends a total economic impact assessment by a 3rd party is needed.

Response. As noted in the Proposed Rule, we are not aware of an available *independent* study (e.g., a study capturing the preparation efforts and costs to develop and Health IT Modules to meet the requirements of the 2014 Edition) that we could rely upon as a basis for estimating the efforts and costs required to develop and prepare health IT to meet the 2015 Edition. We based our cost estimates in the Proposed Rule in part on burden hour estimates provided by the Electronic Health Record Association (EHRA) (a health IT developer association) as well as internal estimates. For this final rule, we have once again relied on burden hour estimates provided by the EHRA in response to the Proposed Rule and internal estimates.

We have also once again generally used the EHRA estimates as a basis for our high estimates. We have used the EHRA estimates in this manner because of the uncertain reliability of the information. It is our understanding that these estimates were based on a survey of EHRA’s members. It is unclear how many of EHRA’s members responded and how each member arrived at their estimates. Further, we cannot rely on these estimates as being generated from an independent, unbiased source because EHRA members must, in some respects, substantiate the costs and fees they charge providers for their certified health IT. We do note, however, that we have also used the EHRA estimates to significantly increase our low estimates.

Based on the estimates provided by the EHRA, by not adopting the 14 proposed certification criteria identified in Table 2 of this final rule and certain other functionality and standards, we have reduced the estimated burden of the 2015 Edition by over 40,000 burden hours per health IT developer. The 14 criteria that were not adopted saved over 25,000 burden hours. An additional 15,000 burden hours were saved through not adopting certain functionality and standards such as user response “tracking” for clinical decision support and drug-drug, drug-allergy interaction checks, a formulary benefit standard, a standard for recording smoking status, a standard for CPOE laboratory orders, and proposals for

certain e-prescribing and C-CDA conformance.

Certification Criteria

We have divided the certification criteria into three categories, each with its own table below. Table 11 is for the new and revised certification criteria associated with the EHR Incentive Programs Stage 3 CEHRT definition and objectives and measures. Table 12 is for the unchanged certification criteria associated with the EHR Incentive Programs Stage 3 CEHRT definition and objectives and measures. These tables also include certification criteria that are mandatory and conditional certification requirements, such as “safety-enhanced design,” and “quality management system,” “accessibility-centered design,” and privacy and security certification criteria as certified Health IT Modules certified to these criteria would be used to meet the CEHRT definition under the EHR Incentive Programs.¹⁸⁵ Table 13 is for all other certification criteria (“Independent Criteria”). We have taken this approach because, based on available data, we can more accurately estimate the number of health IT developers that may develop and prepare Health IT Modules for certification to certification criteria associated with the EHR Incentive Programs.

Health IT Developers and Number of Health IT Modules

New and Revised Stage 3 Criteria

We derive our estimates for the number of health IT developers by beginning with the number of Health IT developers certified to each of the 2014 Edition certification criteria as identified in CHPL data from November 10, 2014. For the new and revised Stage 3 Criteria that correspond to 2014 Edition certification criteria, we have reduced the number of Health IT developers by 30% from the number that certified against the 2014 Edition. We have done this because we have found a 22% drop in the number of health IT developers that certified technology against the 2014 Edition versus the 2011 Edition. We believe that as both interoperability requirements increase by edition and certain health IT developers gain more market share through competition and acquisition of other health IT developers, there will be an even greater drop in the number of

¹⁸⁵ Please see section III.A for explanation of the terms “mandatory” and “conditional” as they apply to certification criteria and the certification of a Health IT Module.

health IT developers that seek certification to the 2015 Edition.

We estimate 2.5 products per health IT developer for each new and revised “Stage 3” criterion. We reached this estimate based both on the number of unique¹⁸⁶ certified products listed on the CHPL as of November 10, 2014 divided by the number of health IT developers certified and stakeholder feedback on our Voluntary Edition proposed rule (79 FR 54474).

We note that these estimates included any new health IT developers.

Unchanged Stage 3 Criteria

For unchanged “Stage 3” criteria, we estimate 5 new health IT developers, each with 1 product. We have attempted to establish a burden estimate for each criterion assuming a health IT developer would be in the same position as a health IT developer that sought certification to the 2011 or 2014 Edition as these 2015 certification criteria are unchanged as compared to those same 2011 and 2014 Edition certification criteria. We do not anticipate more than 5 new health IT developers to certify to these criteria for the market attrition reasons mentioned above. We note for health IT developers that have had products previously certified to the 2014 Edition version of these criteria, we estimate no new costs.

Independent Criteria

For the Independent Criteria, we have only estimated the development and preparation of one Health IT Module to meet these criteria. The Independent Criteria are not currently associated with the EHR Incentive Programs or another HHS payment program. Therefore, we continue to have no reliable basis on which to estimate how many developers and products will be certified to these criteria. We do not include these estimated costs in our overall cost estimate for this final rule.

Average Development and Preparation Hours

Our estimated average development hours are based on feedback we received in response to the RIA we completed for the Proposed Rule and internal estimates for criteria where there is no external data to validly rely upon. As noted above, we have generally used estimates from the Electronic Health Record Association as a basis for our high estimates, where applicable. We have accounted for the reduced burden hours related to functionality and standards not adopted (e.g., “CPOE—laboratory,” “clinical decision support,” and “smoking status,” certification criteria).

We have also attempted to capture developmental synergies where development to a vocabulary and/or

content exchange standard can significantly reduce a health IT developer’s burden when certifying to multiple certification criteria that reference the same vocabulary or content exchange standard. For example, the “transitions of care,” “clinical information reconciliation and incorporation,” “data export,” “view, download, and transmit to 3rd party,” “application access—data category request,” and “application access—all data request” certification criteria included the same content exchange standard and many, if not all, the same vocabulary standards. Based on health IT products certified to the 2014 Edition, we expect health IT developers to certify their products to many or all of these criteria. This will create developmental efficiencies and reduced burden. Similarly, a health IT developer preparing a product for certification to the “social, psychological, and behavioral data” criterion would find synergies in meeting all the measures now included in the criterion as they all rely on LOINC®. We note that our estimates also take into account added burden such as with the Direct criteria, which is a result of adoption of a newer version of the standard and other included interoperability requirements.

Estimated Health IT Developers and Development Hours Per Criterion

TABLE 11—ESTIMATED HEALTH IT DEVELOPERS AND DEVELOPMENT AND PREPARATION HOURS FOR THE 2015 EDITION—NEW AND REVISED CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3 [“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Number of health IT developers who develop product(s) for certification to criterion	Hourly development effort by health IT developer	
				Low avg.	High avg.
1	§ 170.315(a)(5)	Demographics	268.8	1,200	2,000
2	§ 170.315(a)(6)	Problem List	256.9	50	100
3	§ 170.315(a)(9)	Clinical Decision Support	235.2	300	400
4	§ 170.315(a)(12)	Family Health History	250	50	100
5	§ 170.315(a)(13)	Patient-specific Education Resources	249.2	300	400
6	§ 170.315(a)(14)	Implantable Device List	90	700	2,200
7	§ 170.315(b)(1)	Transitions of Care	242.9	3,000	4,000
8	§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation.	224	500	600
9	§ 170.315(b)(3)	Electronic Prescribing	224.7	1,600	2,300
10	§ 170.315(b)(6)	Data Export	228.9	600	1,600
11	§ 170.315(c)(1)	CQMs—record and export	246.4	600	800
12	§ 170.315(c)(2)	CQMs—import and calculate	246.4	600	800
13	§ 170.315(c)(3)	CQMs—report	246.4	600	800
14	§ 170.315(d)(2)	Auditable Events and Tamper-resistance	272.3	50	100
15	§ 170.315(d)(8)	Integrity	312.2	50	100
16	§ 170.315(d)(9)	Trusted Connection	242	100	200
17	§ 170.315(d)(10)	Auditing Actions on Health Information	242	100	200
18	§ 170.315(e)(1)	View, Download, and Transmit to 3rd party.	256.2	1,300	2,000

¹⁸⁶ We attempted to discern how many Complete EHRs and Health IT Modules were used that would

not constitute a newer version of the same technology.

TABLE 11—ESTIMATED HEALTH IT DEVELOPERS AND DEVELOPMENT AND PREPARATION HOURS FOR THE 2015 EDITION—NEW AND REVISED CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued
[“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Number of health IT developers who develop product(s) for certification to criterion	Hourly development effort by health IT developer	
				Low avg.	High avg.
19	§ 170.315(e)(2)	Secure Messaging	246.4	100	200
20	§ 170.315(e)(3)	Patient Health Information Capture	88.9	500	800
21	§ 170.315(f)(1)	Transmission to Immunization Registries	220.5	1,000	1,600
22	§ 170.315(f)(2)	Transmission to Public Health Agencies—syndromic surveillance.	100	600	800
23	§ 170.315(f)(4)	Transmission to Cancer Registries	22.4	800	1,000
24	§ 170.315(f)(5)	Transmission to Public Health Agencies—electronic case reporting.	21	600	800
25	§ 170.315(f)(6)	Transmission to Public Health Agencies—antimicrobial use and resistance reporting.	21	1,000	1,400
26	§ 170.315(f)(7)	Transmission to Public Health Agencies—health care surveys.	21	1,000	1,400
27	§ 170.315(g)(1)	Automated Numerator Recording	113.4	800	1,200
28	§ 170.315(g)(2)	Automated Measure Calculation	264.6	1,000	1,600
29	§ 170.315(g)(3)	Safety-enhanced Design	266	300	400
30	§ 170.315(g)(4)	Quality Management System	401.8	50	160
31	§ 170.315(g)(5)	Accessibility-Centered Design	401.8	50	100
32	§ 170.315(g)(6)	Consolidated CDA Creation Performance	242	400	900
33	§ 170.315(g)(7)	Application Access—Patient Selection	242	300	400
34	§ 170.315(g)(8)	Application Access—Data Category Request.	242	300	400
35	§ 170.315(g)(9)	Application Access—All Data Request	242	300	400
36	§ 170.315(h)(1)	Direct Project	140	800	1,100
37	§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM.	70	800	1,100

TABLE 12—ESTIMATED HEALTH IT DEVELOPERS AND DEVELOPMENT AND PREPARATION HOURS FOR PROPOSED UNCHANGED CERTIFICATION CRITERIA—CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3
[“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Number of health IT developers who develop product(s) for certification to criterion	Hourly development effort by health IT developer	
				Low avg.	High avg.
1	§ 170.315(a)(1)	CPOE—medications	5	50	100
2	§ 170.315(a)(2)	CPOE—laboratory	5	50	100
3	§ 170.315(a)(3)	CPOE—diagnostic imaging	5	50	100
4	§ 170.315(a)(4)	DD/DAI Checks for CPOE	5	50	100
5	§ 170.315(a)(8)	Medication List	5	50	100
6	§ 170.315(a)(9)	Medication Allergy List	5	50	100
7	§ 170.315(a)(10)	Drug-formulary and Preferred Drug List Checks.	5	50	100
8	§ 170.315(a)(11)	Smoking Status	5	50	100
9	§ 170.315(d)(1)	Authentication, Access Control, Authorization.	5	50	100
10	§ 170.315(d)(3)	Audit Report(s)	5	50	100
11	§ 170.315(d)(4)	Amendments	5	50	100
12	§ 170.315(d)(5)	Automatic Access Time-out	5	50	100
13	§ 170.315(d)(6)	Emergency Access	5	50	100
14	§ 170.315(d)(7)	End-User Device Encryption	5	50	100
15	§ 170.315(f)(3)	Transmission to Public Health Agencies—reportable laboratory tests and values/results.	5	400	600

TABLE 13—ESTIMATED DEVELOPMENT AND PREPARATION HOURS FOR THE 2015 EDITION—CRITERIA NOT ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3
[“Independent Criteria”]

Item No.	CFR text	Certification criterion name	Hourly development effort by health IT developer	
			Low avg.	High avg.
1	§ 170.315(a)(15)	Social, Psychological, and Behavioral Data	800	1,000
2	§ 170.315(b)(4)	Common Clinical Data Set Summary Record—Create	1,600	2,200
3	§ 170.315(b)(5)	Common Clinical Data Set Summary Record—Receive	1,600	2,200
4	§ 170.315(b)(7)	Data Segmentation for Privacy—send	800	1,300
5	§ 170.315(b)(8)	Data Segmentation for Privacy—receive	800	1,300
6	§ 170.315(b)(9)	Care Plan	700	1,000
7	§ 170.315(c)(4)	CQMs—filter	1,000	1,500
8	§ 170.315(d)(9)	Accounting of Disclosures	400	600

Health IT Developer Hourly Cost and Cost Range

We have based the effort levels on the hours necessary for a software developer to develop and prepare the health IT for testing and certification. These hours are identified in Tables 11–13 above.

The U.S. Department of Labor, Bureau of Labor Statistics estimates that the median hourly wage for a software developer is \$45.92.¹⁸⁷ 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 \$63 per hour.

To calculate our cost estimates for each certification criterion in the tables below, we have multiplied both the average low and average high number of development and preparation hours in Tables 11–13 by \$63. For tables 14, 15, and 16, dollar amounts are expressed in 2014 dollars.

Estimated Cost Per Criterion for Health IT Developers

TABLE 14—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS —2015 EDITION NEW AND REVISED CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3
[“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Average cost estimates (\$)	
			Average low (\$)	Average high (\$)
1	§ 170.315(a)(5)	Demographics	20,321,280	33,868,800
2	§ 170.315(a)(6)	Problem List	809,235	1,618,470
3	§ 170.315(a)(9)	Clinical Decision Support	4,445,280	5,927,040
4	§ 170.315(a)(12)	Family Health History	787,500	1,575,000
5	§ 170.315(a)(13)	Patient-specific Education Resources	4,709,880	6,279,840
6	§ 170.315(a)(14)	Implantable Device List	3,969,000	12,474,000
7	§ 170.315(b)(1)	Transitions of Care	45,908,100	61,210,800
8	§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation	7,056,000	8,467,200
9	§ 170.315(b)(3)	Electronic Prescribing	22,649,760	32,559,030
10	§ 170.315(b)(6)	Data Export	8,652,420	23,073,120
11	§ 170.315(c)(1)	CQMs—record and export	9,313,920	12,418,560
12	§ 170.315(c)(2)	CQMs—import and calculate	9,313,920	12,418,560
13	§ 170.315(c)(3)	CQMs—report	9,313,920	12,418,560
14	§ 170.315(d)(2)	Auditable Events and Tamper-resistance	857,745	1,715,490
15	§ 170.315(d)(8)	Integrity	983,430	1,966,860
16	§ 170.315(d)(9)	Trusted Connection	1,524,600	3,049,200
17	§ 170.315(d)(10)	Auditing Actions on Health Information	1,524,600	3,049,200
18	§ 170.315(e)(1)	View, Download, and Transmit to 3rd party	20,982,780	32,281,200
19	§ 170.315(e)(2)	Secure Messaging	1,552,320	3,104,640
20	§ 170.315(e)(3)	Patient Health Information Capture	2,800,350	4,480,560
21	§ 170.315(f)(1)	Transmission to Immunization Registries	13,891,500	22,226,400
22	§ 170.315(f)(2)	Transmission to Public Health Agencies—syndromic surveillance.	3,780,000	5,040,000
23	§ 170.315(f)(4)	Transmission to Cancer Registries	1,128,960	1,411,200
24	§ 170.315(f)(5)	Transmission to Public Health Agencies—electronic case reporting.	793,800	1,058,400
25	§ 170.315(f)(6)	Transmission to Public Health Agencies—antimicrobial use and resistance reporting.	1,323,000	1,852,200

¹⁸⁷ <http://www.bls.gov/oes/current/oes151132.htm>.

TABLE 14—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS—2015 EDITION NEW AND REVISED CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued
[“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Average cost estimates (\$)	
			Average low (\$)	Average high (\$)
26	§ 170.315(f)(7)	Transmission to Public Health Agencies—health care surveys.	1,323,000	1,852,200
27	§ 170.315(g)(1)	Automated Numerator Recording	5,715,360	8,573,040
28	§ 170.315(g)(2)	Automated Measure Calculation	16,669,800	26,671,680
29	§ 170.315(g)(3)	Safety-enhanced Design	5,027,400	6,703,200
30	§ 170.315(g)(4)	Quality Management System	1,265,670	4,050,144
31	§ 170.315(g)(5)	Accessibility-Centered Design	1,265,670	2,531,340
32	§ 170.315(g)(6)	Consolidated CDA Creation Performance	6,098,400	13,721,400
33	§ 170.315(g)(7)	Application Access—Patient Selection	4,573,800	6,098,400
34	§ 170.315(g)(8)	Application Access—Data Category Request	4,573,800	6,098,400
35	§ 170.315(g)(9)	Application Access—All Data Request	4,573,800	6,098,400
36	§ 170.315(h)(1)	Direct Project	7,056,000	9,702,000
37	§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM	3,528,000	4,851,000

TABLE 15—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS—2015 EDITION UNCHANGED CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3
[“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Average cost estimates (\$)	
			Average low (\$)	Average high (\$)
1	§ 170.315(a)(1)	CPOE—medications	15,750	31,500
2	§ 170.315(a)(2)	CPOE—laboratory	15,750	31,500
3	§ 170.315(a)(3)	CPOE—diagnostic imaging	15,750	31,500
4	§ 170.315(a)(4)	DD/DAI Checks for CPOE	15,750	31,500
5	§ 170.315(a)(8)	Medication List	15,750	31,500
6	§ 170.315(a)(9)	Medication Allergy List	15,750	31,500
7	§ 170.315(a)(10)	Drug-Formulary and Preferred Drug List Checks	15,750	31,500
8	§ 170.315(a)(11)	Smoking Status	15,750	31,500
9	§ 170.315(d)(1)	Authentication, Access Control, Authorization	15,750	31,500
10	§ 170.315(d)(3)	Audit Report(s)	15,750	31,500
11	§ 170.315(d)(4)	Amendments	15,750	31,500
12	§ 170.315(d)(5)	Automatic Access Time-Out	15,750	31,500
13	§ 170.315(d)(6)	Emergency Access	15,750	31,500
14	§ 170.315(d)(7)	End-User Device Encryption	15,750	31,500
15	§ 170.315(f)(3)	Transmission to Public Health Agencies—reportable laboratory tests and values/results.	126,000	189,000

TABLE 16—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION—2015 EDITION CRITERIA NOT ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3
[“Independent Criteria”]

Item No.	CFR text	Certification criterion name	Average cost estimates (\$)	
			Average low (\$)	Average high (\$)
1	§ 170.315(a)(15)	Social, Psychological, and Behavioral Data	50,400	63,000
2	§ 170.315(b)(4)	Common Clinical Data Set Summary Record—Create	100,800	138,600
3	§ 170.315(b)(5)	Common Clinical Data Set Summary Record—Receive	100,800	138,600
4	§ 170.315(b)(7)	Data Segmentation for Privacy—send	50,400	81,900
5	§ 170.315(b)(8)	Data Segmentation for Privacy—receive	50,400	81,900
6	§ 170.315(b)(9)	Care Plan	44,100	63,000
7	§ 170.315(c)(4)	CQMs—filter	63,000	94,500
8	§ 170.315(d)(9)	Accounting of Disclosures	25,200	37,800

ii. Overall Development and Preparation Costs Over a Four-Year Period

We estimate the development and preparation costs over a four-year period because a four-year period aligns with our estimated publication date for a subsequent final rule (2015) and the year in which CMS proposes that participants in the EHR Incentive Programs *must* use health IT certified to the 2015 Edition (2018) (see the EHR Incentive Programs Stage 3 and Modifications final rule published elsewhere in this issue of the **Federal Register**).

In total, we estimate the overall costs to develop and prepare health IT for certification over a four-year period to be \$260.44 million to \$403.19 million, with a cost mid-point of approximately \$331.82 million. Evenly distributed over

calendar years 2015 through 2018, the cost range would be \$65.11 million to \$100.79 million per year with an annual cost mid-point of approximately \$82.95 million. However, we project these costs to be unevenly distributed. We estimate the distribution as follows: 2015 (15%); 2016 (35%); 2017 (35%); and 2018 (15%). We reached this distribution based on these assumptions and information:

- We expect for health IT developers to spend the rest of the year preparing and developing their health IT to meet the 2015 Edition. We note that we lowered the percentage to 15% for 2015 from 25% in the Proposed Rule due to the later-than-anticipated publication date of this final rule. We redistributed the 10% over 2016 and 2017.
- We expect health IT developers to aggressively work in 2016 and 2017 to

prepare and develop their health IT to meet the 2015 Edition as the compliance date for the EHR Incentive Programs CEHRT definition draws near (*i.e.*, 2018) and because health IT certified to the 2015 Edition *could* be used in 2017 under the EHR Incentive Programs CEHRT definition finalized in the EHR Incentive Programs Stage 3 and Modifications final rule (published elsewhere in this issue of the **Federal Register**).

- We expect health IT developers to continue to prepare and develop health IT to the 2015 Edition in 2018 based on their approach to the 2014 Edition.

Table 17 below represents the costs attributable to this proposed rule distributed as discussed above. The dollar amounts expressed in Table 17 are expressed in 2014 dollars.

TABLE 17—DISTRIBUTED TOTAL 2015 EDITION DEVELOPMENT AND PREPARATION COSTS FOR HEALTH IT DEVELOPERS (4-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (%)	Total low cost estimate (\$M)	Total high cost estimate (\$M)	Total average cost estimate (\$M)
2015	15	39.07	60.48	49.77
2016	35	91.15	141.12	116.14
2017	35	91.15	141.12	116.14
2018	15	39.07	60.48	49.77
4-Year Totals	260.44	403.19	331.82

iii. Testing and Certification Costs for the 2015 Edition

In the RIA of the Permanent Certification Program final rule, we estimated the costs for testing and certification of technologies that would be used for providers to attempt to achieve EHR Incentive Programs Stages 1–3.¹⁸⁸ These costs were based on the requirements of the certification program and a two-year rulemaking cycle for the CEHRT definition and each EHR Incentive Programs stage. We believe the costs we attributed to testing and certification of technologies in support of EHR Incentive Programs Stage 2 in the Permanent Certification Program final rule would encompass the actual testing and certification of technologies to both the 2014 and 2015 Editions. This assessment is based on the number of technologies currently certified to the 2014 Edition and our projections in this proposed rule for the number of technologies that would likely be tested and certified to the 2015 Edition. Further, we note that the estimated costs in the Permanent Certification Program final rule

included costs for surveillance of technologies and also estimated the costs for testing and certification above what we understand are the cost ranges charged by ONC–ACBs today.

iv. New and Revised Principles of Proper Conduct Estimated Costs to ONC–ACB

We have estimated the costs associated with new and revised PoPC finalized in this final rule. For reporting requirements under 45 CFR 170.523(f), (m), and (n), we have used burden hour estimates provided in the Proposed Rule (80 FR 16893). For 45 CFR 170.523(i), we have increased the burden hours based on the quarterly reporting requirements and the nature of what must be reported. For 45 CFR 170.523(g) and (k), we have established burden hour estimates based on the number of certifications performed per year by ONC–ACBs.

We believe that an employee equivalent to the Federal Classification of GS–12 Step 1 could report the required information for 45 CFR 170.523(f), retain the records under 45

CFR 170.523(g), compile and submit surveillance results quarterly per 45 CFR 170.523(i), collect adaptations/updates quarterly per 45 CFR 170.523(m), and compile and submit complaints per 45 CFR 170.523(n). We believe that an employee equivalent to the Federal Classification of GS–14 Step 1 could verify health IT developers' compliance with 45 CFR 170.523(k). We have utilized the corresponding employee hourly rates for the locality pay area of Washington, D.C., as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the specified tasks. We have calculated these costs by assuming that an ONC–ACB 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. Our cost estimates are expressed in Table 18 below and are expressed in 2015 dollars (rounded).

¹⁸⁸ 76 FR 1318.

TABLE 18—ANNUAL COSTS FOR AN ONC-ACB TO COMPLY WITH NEW AND REVISED POPC

Program requirement	Employee equivalent	Annual burden hours per ONC-ACB	Employee hourly wage rate (\$)	Employee benefits hourly cost (\$)	Total cost per ONC-ACB (\$)
45 CFR 170.523(f)	GS-12, Step 1	230	36.60	\$13.18	\$11,449.40
45 CFR 170.523(g)	GS-12, Step 1	1,000	36.60	13.18	49,780
45 CFR 170.523(i)	GS-12, Step 1	80	36.60	13.18	3,982.40
45 CFR 170.523(k)	GS-14, Step 1	1,000	51.43	18.51	69,940
45 CFR 170.523(m)	GS-12, Step 1	4	36.60	13.18	199.12
45 CFR 170.523(n)	GS-12, Step 1	4	36.60	13.18	199.12
Total					135,550.04

We estimate the total annual costs to be \$406,650.12 based on three ONC-ACBs.

Costs to Health IT Developers

Certain new and revised PoPC create indirect costs on health IT developers,

which we have attempted to estimate in this final rule below. We have estimated the burden hours to the extent possible. We have used the same cost factors as discussed above. We have estimated 402 health IT developers based on the

highest estimated number of health IT developers we expect to be certified to a 2015 Edition certification criterion (see Table 11 above). Our cost estimates are expressed in Table 19 below and are expressed in 2015 dollars (rounded).

TABLE 19—ANNUAL COSTS FOR HEALTH IT DEVELOPERS TO COMPLY WITH TRANSPARENCY AND REPORTING REQUIREMENTS

Program requirement	Employee equivalent	Annual burden hours per health IT developer	Employee hourly wage rate	Employee benefits hourly cost	Total number of health IT developers	Total cost (\$M)
45 CFR 170.523(k)	GS-14, Step 1	100	\$51.43	\$18.51	402	2.81
45 CFR 170.523(m)	GS-12, Step 1	8	36.60	13.18	402	.16
Total Costs						2.97

b. Benefits

As noted above, we expect that health IT developers will recover an appropriate rate of return for their investments in developing and preparing their health IT for certification to the 2015 Edition certification criteria adopted in this final rule. However, we do not have data available to quantify these benefits or other benefits that will likely arise from health IT developers certifying their health IT to the 2015 Edition.

We believe that there will be several significant benefits that may arise from this final rule for patients, health care providers, and health IT developers. The 2015 Edition continues to improve health IT interoperability through the adoption of new and updated standards and implementation specifications. For example, many adopted certification criteria include standards and implementation specifications for interoperability that directly support the EHR Incentive Programs, which include objectives and measures for the interoperable exchange of health information and for providing patients electronic access to their health information in structured formats. In

addition, 2015 Edition certification criteria that support the collection of patient data that could be used to address health disparities would not only benefit patients, but the entire health care delivery system through improved quality of care. The 2015 Edition also supports usability and patient safety through new and enhanced certification requirements for health IT.

This final rule also makes the ONC Health IT Certification Program open and accessible to more types of health IT and for health IT that supports a variety of care and practice settings. This should benefit health IT developers, providers practicing in other care/practice settings, and consumers through the availability and use of certified health IT that includes capabilities that promote interoperability and enhanced functionality.

We note that, in general, these benefits will be realized only if health care providers actually adopt new technology. As discussed elsewhere in this RIA, we believe that such adoption—and thus the benefits noted in this section—would be

overwhelmingly attributable to CMS's final rule.

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 health IT developers that pursue certification under the ONC Health IT 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 in 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 \$27.5 million in

annual receipts¹⁸⁹ 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 health IT product that will be certified to the 2015 Edition under the ONC Health IT 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 health IT developers that pursue certification under the ONC Health IT 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 health IT 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 health IT developers that have had Complete EHRs and/or EHR Modules certified to the 2011 Edition have less than 51 employees.

We estimate that this final rule would have effects on health IT developers that are likely to pursue certification under the ONC Health IT Certification Program, some of which may be small entities. However, we believe that we have adopted 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 final rule. We note that this final rule does not impose the costs cited in the RIA as compliance costs, but rather as investments which these health IT developers voluntarily take on and may expect to recover with an appropriate rate of return. Accordingly, we do not believe that the final rule will create a significant impact on a substantial number of small entities. Additionally, the Secretary certifies that this final 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 final 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 have adopted.

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 \$144 million. This final rule will not impose an unfunded mandate on State, local, and tribal governments or on the private sector that will reach the threshold level.

OMB reviewed this final 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 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. Amend § 170.102 by:

■ a. Removing the definitions for “Base EHR”, “Certified EHR Technology”, “Common MU Data Set”, and “EHR Module”; and

■ b. Adding in alphanumeric order the definitions for “2014 Edition Base EHR”, “2015 Edition Base EHR”, “2015 Edition health IT certification criteria”, “Common Clinical Data Set”, “Device identifier”, “Global Unique Device Identification Database (GUDID)”, “Health IT Module”, “Implantable device”, “Production identifier”, and “Unique device identifier”.

The revisions read as follows:

§ 170.102 Definitions.

2014 Edition 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:

(i) For at least one of the four criteria adopted at § 170.314(a)(1), (18), (19), or (20);

(ii) At § 170.314(a)(3);

(iii) At § 170.314(a)(5) through (8);

(iv) Both § 170.314(b)(1) and (2); or, both § 170.314(b)(8) and (h)(1); or § 170.314(b)(1) and (2) combined with either § 170.314(b)(8) or (h)(1), or both § 170.314(b)(8) and (h)(1);

(v) At § 170.314(b)(7);

(vi) At § 170.314(c)(1) through (3);

(vii) At § 170.314(d)(1) through (8);

(4) Has been certified to the certification criteria at § 170.314(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.

* * * * *

2015 Edition Base EHR means an electronic record of health-related information on an individual that:

¹⁸⁹ 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.

(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; and

(3) Has been certified to the certification criteria adopted by the Secretary in § 170.315(a)(1), (2), or (3); (a)(5) through (9); (a)(11); (a)(15); (b)(1) and (6); (c)(1); (g)(7) through (9); and (h)(1) or (2);

2015 Edition health IT certification criteria means the certification criteria in § 170.315.

* * * * *

Common Clinical Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) *Patient name*. For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(2) *Sex*. (i) No required standard for certification to the 2014 Edition EHR certification criteria.

(ii) The standard specified in § 170.207(n)(1) for certification to the 2015 Edition health IT certification criteria.

(3) *Date of birth*. For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(4) *Race*. (i) The standard specified in § 170.207(f)(1) for certification to the 2014 Edition EHR certification criteria.

(ii) For certification to the 2015 Edition health IT certification criteria: (A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).

(5) *Ethnicity*. (i) The standard specified in § 170.207(f)(1) for certification to the 2014 Edition EHR certification criteria.

(ii) For certification to the 2015 Edition health IT certification criteria: (A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).

(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 Health IT certification criteria.

(7) *Smoking status*. For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria: The standard specified in § 170.207(h).

(8) *Problems*. (i) At a minimum, the standard specified in § 170.207(a)(3) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(a)(4) for certification to the 2015 Edition Health IT certification criteria.

(9) *Medications*. (i) At a minimum, the standard specified in § 170.207(d)(2) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(d)(3) for certification to the 2015 Edition Health IT certification criteria.

(10) *Medication allergies*. (i) At a minimum, the standard specified in § 170.207(d)(2) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(d)(3) for certification to the 2015 Edition Health IT certification criteria.

(11) *Laboratory test(s)*. (i) At a minimum, the standard specified in § 170.207(c)(2) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(c)(3) for certification to the 2015 Edition Health IT certification criteria.

(12) *Laboratory value(s)/result(s)*. For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(13) *Vital signs*. (i) Height/length, weight, blood pressure, and BMI for certification to the 2014 Edition EHR certification criteria.

(ii) For certification to the 2015 Edition Health IT certification criteria: (A) The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and

(B) In accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).

(C) *Optional*. The patient's BMI percentile per age and sex for youth 2–20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance

with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2–20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.

(14) *Care plan field(s), including goals and instructions*. For certification to the 2014 Edition EHR certification criteria.

(15) *Procedures*—(i)(A) At a minimum, the version of the standard specified in § 170.207(a)(3) for certification to the 2014 Edition EHR certification criteria and § 170.207(a)(4) for certification to the 2015 Edition health IT certification criteria, or § 170.207(b)(2); or

(B) For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) for certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(ii) *Optional*. The standard specified in § 170.207(b)(4) for certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(16) *Care team member(s)*. For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(17) *Immunizations*. In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4) for certification to the 2015 Edition health IT certification criteria.

(18) *Unique device identifier(s) for a patient's implantable device(s)*. In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.

(19) *Assessment and plan of treatment*. For certification to the 2015 Edition health IT certification criteria:

(i) In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or

(ii) In accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).

(20) *Goals*. In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.

(21) *Health concerns*. In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4)

for certification to the 2015 Edition health IT certification criteria.

* * * * *

Device identifier is defined as it is in 21 CFR 801.3.

* * * * *

Global Unique Device Identification Database (GUDID) is defined as it is in 21 CFR 801.3.

Health IT Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

* * * * *

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.

§ 170.200 [Amended]

■ 3. In § 170.200, remove the term “EHR Modules” and add in its place “Health IT Modules.”

■ 4. Amend § 170.202 by—

- a. Revising the section heading;
- b. Revising paragraph (a); and
- c. Adding paragraph (e).

The additions and revisions read as follows:

§ 170.202 Transport standards and other protocols.

* * * * *

(a) *Direct Project*—(1) *Standard*. ONC Applicability Statement for Secure Health Transport, Version 1.0 (incorporated by reference in § 170.299).

(2) *Standard*. ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference in § 170.299).

* * * * *

(e) *Delivery notification*—(1) *Standard*. ONC Implementation Guide for Delivery Notification in Direct (incorporated by reference in § 170.299).

(2) [Reserved]

■ 5. Amend § 170.204 by—

- a. Revising paragraphs (a) and (b)(2); and
- b. Adding paragraphs (b)(3) and (4).

The additions and revisions read as follows:

§ 170.204 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 (incorporated by reference in § 170.299).

(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 (incorporated by reference in § 170.299).

(3) *Standard*. HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application (“Infobutton”), Knowledge Request, Release 2 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1 (incorporated by reference in § 170.299).

(4) *Standard*. HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application (“Infobutton”), Knowledge Request, Release 2 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4 (incorporated by reference in § 170.299).

■ 6. Amend § 170.205 by—

- a. Adding paragraphs (a)(4), (d)(4), and (e)(4);
- b. Revising paragraphs (h), (i), and (k);
- c. Reserving paragraphs (1), (m), (n), and (q); and
- d. Adding paragraphs (o), (p), (r), and (s).

The additions and revisions read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(a) * * *

(4) *Standard*. HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299).

* * * * *

(d) * * *

(4) *Standard*. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications*. PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015 (incorporated by reference in § 170.299) and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015;

Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings (incorporated by reference in § 170.299).

(e) * * *

(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 (incorporated by reference in § 170.299) and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015 (incorporated by reference in § 170.299).

* * * * *

(h) *Clinical quality measure data import, export and reporting*. (1) *Standard*. HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture (incorporated by reference in § 170.299).

(2) *Standard*. HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material and HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting Material (incorporated by reference in § 170.299).

(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*. HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, Volume 1—Introductory Material and HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material (incorporated by reference in § 170.299).

* * * * *

(k) *Clinical quality measure aggregate reporting*. (1) *Standard*. Quality Reporting Document Architecture

Category III, Implementation Guide for CDA Release 2 (incorporated by reference in § 170.299).

(2) *Standard*. Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014 (incorporated by reference in § 170.299).

(l) [Reserved]

(m) [Reserved]

(n) [Reserved]

(o) *Data segmentation for privacy*—(1) *Standard*. HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (incorporated by reference in § 170.299).

(2) [Reserved]

(p) *XDM package processing*—(1) *Standard*. IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) (incorporated by reference in § 170.299).

(2) [Reserved]

(q) [Reserved]

(r) *Public health—antimicrobial use and resistance information*—(1) *Standard*. The following sections of HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (incorporated by reference in § 170.299). Technology is only required to conform to the following sections of the implementation guide:

(i) HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69–72);

(ii) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54–56); and

(iii) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56–58).

(2) [Reserved]

(s) *Public health—health care survey information*—(1) *Standard*. HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material and HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material (incorporated by reference in § 170.299).

(2) [Reserved]

■ 7. Amend § 170.207 by—

■ a. Adding paragraphs (a)(4), (c)(3), (d)(3), (e)(3) and (4);

■ b. Revising paragraphs (f) and (g); and

■ c. Reserving paragraphs (k) and (l); and

■ d. Adding paragraphs (m), (n), (o), (p), (q), (r), and (s).

The additions and revisions read as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

* * * * *

(a) * * *

(4) *Standard*. IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release (incorporated by reference in § 170.299).

* * * * *

(c) * * *

(3) *Standard*. Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).

(d) * * *

(3) *Standard*. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release (incorporated by reference in § 170.299).

(e) * * *

(3) *Standard*. HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 (incorporated by reference in § 170.299).

(4) *Standard*. National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015 (incorporated by reference in § 170.299).

(f) *Race and Ethnicity*—(1) *Standard*. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (incorporated by reference in § 170.299).

(2) *Standard*. CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (incorporated by reference in § 170.299).

(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*. Request for Comments (RFC) 5646 (incorporated by reference in § 170.299).

* * * * *

(k) [Reserved]

(l) [Reserved]

(m) *Numerical references*—(1) *Standard*. The Unified Code of Units of Measure, Revision 1.9 (incorporated by reference in § 170.299).

(2) [Reserved]

(n) *Sex*—(1) *Standard*. Birth sex must be coded in accordance with HL7

Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), attributed as follows:

(i) *Male*. M

(ii) *Female*. F

(iii) *Unknown*. nullFlavor UNK

(2) [Reserved]

(o) *Sexual orientation and gender identity*—(1) *Standard*. Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED CTsupreg; codes specified in paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

(i) *Lesbian, gay or homosexual*.

38628009

(ii) *Straight or heterosexual*. 20730005

(iii) *Bisexual*. 42035005

(iv) *Something else, please describe*. nullFlavor OTH

(v) *Don't know*. nullFlavor UNK

(vi) *Choose not to disclose*. nullFlavor ASKU

(2) *Standard*. Gender identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

(i) *Male*. 446151000124109

(ii) *Female*. 446141000124107

(iii) *Female-to-Male (FTM)/ Transgender Male/Trans Man*.

407377005

(iv) *Male-to-Female (MTF)/ Transgender Female/Trans Woman*.

407376001

(v) *Genderqueer, neither exclusively male nor female*. 446131000124102

(vi) *Additional gender category or other, please specify*. nullFlavor OTH

(vii) *Choose not to disclose*.

nullFlavor ASKU

(p) *Social, psychological, and behavioral data*—(1) *Financial resource strain*. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5.

(2) *Education*. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with LOINC®

code 63504–5 and LOINC® answer list ID LL1069–5.

(3) *Stress*. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with the LOINC® code 76542–0 and LOINC® answer list LL3267–3.

(4) *Depression*. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with LOINC® codes 55757–9, 44250–9 (with LOINC® answer list ID LL358–3), 44255–8 (with LOINC® answer list ID LL358–3), and 55758–7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

(5) *Physical activity*. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with LOINC® codes 68515–6 and 68516–4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1).

(6) *Alcohol use*. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with LOINC® codes 72109–2, 68518–0 (with LOINC® answer list ID LL2179–1), 68519–8 (with LOINC® answer list ID LL2180–9), 68520–6 (with LOINC® answer list ID LL2181–7), and 75626–2.

(7) *Social connection and isolation*. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with the LOINC® codes 76506–5, 63503–7 (with LOINC answer list ID LL1068–7), 76508–1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509–9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76510–7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511–5 (with LOINC answer list ID LL963–0), and 76512–3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

(8) *Exposure to violence (intimate partner violence)*. Exposure to violence: Intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section and attributed with the LOINC® code

76499–3, 76500–8 (with LOINC® answer list ID LL963–0), 76501–6 (with LOINC® answer list ID LL963–0), 76502–4 (with LOINC® answer list ID LL963–0), 76503–2 (with LOINC® answer list ID LL963–0), and 76504–0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

(q) *Patient matching*. (1) *Phone number standard*. ITU–T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, email addresses and web addresses (incorporated by reference in § 170.299); and ITU–T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service: The international public telecommunication numbering plan (incorporated by reference in § 170.299).

(2) [Reserved]

(r) *Provider type*. (1) *Standard*. Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015 (incorporated by reference in § 170.299).

(2) [Reserved]

(s) *Patient insurance*. (1) *Standard*. Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011) (incorporated by reference in § 170.299).

(2) [Reserved]

■ 8. In § 170.210:

- a. Add paragraph (a)(2)
- b. Revise paragraphs (c) and (e)(1)(i);
- c. Amend paragraphs (e)(3) by removing the term “EHR technology” and adding in its place “health IT”; and
- d. Revise paragraph (h).

The addition and revisions read as follows:

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

* * * * *

(a) * * *

(2) *General*. Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2, October 8, 2014 (incorporated by reference in § 170.299).

* * * * *

(c) *Hashing of electronic health information*. (1) *Standard*. A hashing algorithm with a security strength equal

to or greater than SHA–1 (Secure Hash Algorithm (SHA–1)) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180–4 (March 2012)).

(2) *Standard*. A hashing algorithm with a security strength equal to or greater than SHA–2 as specified by NIST in FIPS Publication 180–4 (August 2015) (incorporated by reference in § 170.299).

* * * * *

(e) * * *

(1)(i) The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified in § 170.210(h) and changes to user privileges when health IT is in use.

* * * * *

(h) *Audit log content*. ASTM E2147–01 (Reapproved 2013), (incorporated by reference in § 170.299).

■ 9. In § 170.299:

- a. Revise paragraph (c)(1).
- b. Add paragraphs (d)(10) through (16), (e)(3) and (f)(15) through (29).
- c. Redesignate paragraphs (g), (h), (i), (j), (k), (l), (m), and (n) as paragraphs (h), (j), (k), (l), (m), (o), (q), and (r), respectively.
- d. Add new paragraphs (g), (i), (n), and (p).
- e. Amend newly redesignated paragraph (h) by revising paragraph (h) introductory text and adding paragraph (h)(3).
- f. Amend newly redesignated paragraph (l) by adding paragraphs (l)(3) and (4).
- g. Amend newly redesignated paragraph (m) by revising paragraph (m) introductory text.
- h. Amend newly redesignated paragraph (o) by revising paragraph (o) introductory text and adding paragraphs (o)(3) and (4).
- i. Amend newly redesignated paragraph (q) by adding paragraphs (q)(6) and (7).

The additions and revisions read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(c) * * *

(1) ASTM E2147–01 (Reapproved 2013) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved March 1, 2013, IBR approved for § 170.210(h).

* * * * *

(d) * * *

(10) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015, IBR approved for § 170.205(d).

(11) Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, IBR approved for § 170.205(d).

(12) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 1, 2014, IBR approved for § 170.205(e).

(13) HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015, IBR approved for § 170.205(e).

(14) HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015, IBR approved for § 170.207(e).

(15) National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015, IBR approved for § 170.207(e).

(16) CDC Race and Ethnicity Code Set Version 1.0 (March 2000), IBR approved for § 170.207(f).

(e) * * *

(3) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015, IBR approved for § 170.207(r).

(f) * * *

(15) HL7 Version 3 Standard: Context Aware Retrieval Application (“Infobutton”), Knowledge Request, Release 2, 2014 Release, IBR approved for § 170.204(b).

(16) HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 9, 2013, IBR approved for § 170.204(b).

(17) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4, June 13, 2014, IBR approved for § 170.204(b).

(18) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(19) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(20) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material, June 2015, IBR approved for § 170.205(h).

(21) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting Material, June 2015, IBR approved for § 170.205(h).

(22) HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 1—Introductory Material, April 2015, IBR approved for § 170.205(i).

(23) HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material, April 2015, IBR approved for § 170.205(i).

(24) Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014, IBR approved for § 170.205(k).

(25) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, Part 1: CDA R2 and Privacy Metadata Reusable Content Profile, May 16, 2014, IBR approved for § 170.205(o).

(26) HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1 (U.S. Realm), August 9, 2013, IBR approved for § 170.205(r).

(27) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material, December 2014, IBR approved for § 170.205(s).

(28) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, December 2014, IBR approved for § 170.205(s).

(29) HL7 Version 3 (V3) Standard, Value Sets for Administrative Gender and Null Flavor, published August 1, 2013, IBR approved for § 170.207(n) and (o).

(g) Integrating the Healthcare Enterprise (IHE), 820 Jorie Boulevard, Oak Brook, IL, Telephone (630) 481-1004, <http://http://www.ihe.net/>.

(1) IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b), Transactions Part B—Sections 3.29—2.43, Revision 7.0, August 10, 2010, IBR approved for § 170.205(p).

(2) [Reserved]

(h) Internet Engineering Task Force (IETF) Secretariat, c/o Association Management Solutions, LLC (AMS), 48377 Fremont Blvd., Suite 117, Fremont, CA, 94538, Telephone (510) 492-4080, <http://www.ietf.org/rfc.html>.

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(3) Request for Comment (RFC) 5646, “Tags for Identifying Languages, September 2009,” copyright 2009, IBR approved for § 170.207(g).

(i) International Telecommunication Union (ITU), Place des Nations, 1211 Geneva 20 Switzerland, Telephone (41) 22 730 511, <http://www.itu.int/en/pages/default.aspx>.

(1) ITU-T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, e-mail addresses and web addresses, February 2001, IBR approved for § 170.207(q).

(2) ITU-T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service, The international public telecommunication numbering plan, November 2010, IBR approved for § 170.207(q).

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(1) * * *

(3) Annex A: Federal Information Processing Standards (FIPS) Publication 140-2, Security Requirements for Cryptographic Modules, October 8, 2014, IBR approved for § 170.210(a).

(4) FIPS PUB 180-4, Secure Hash Standard (August 2015), IBR approved for § 170.210(c).

(m) Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW., Washington, DC 20201, <http://healthit.hhs.gov>.

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(n) Public Health Data Standards Consortium, 111 South Calvert Street, Suite 2700, Baltimore, MD 21202, <http://www.phdsc.org/>.

(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011), IBR approved for § 170.207(s).

(2) [Reserved]

(o) Regenstrief Institute, Inc., LOINC® c/o Regenstrief Center for Biomedical Informatics, Inc., 410 West 10th Street, Suite 2000, Indianapolis, IN 46202-3012, <http://loinc.org/>.

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(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, IBR approved for § 170.207(c).

(4) The Unified Code of Units for Measure, Revision 1.9, October 23, 2013, IBR approved for § 170.207.

(p) The Direct Project, c/o the Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW., Washington, DC 20201, <http://healthit.hhs.gov>.

(1) Applicability Statement for Secure Health Transport, Version 1.2, August 2015, IBR approved for § 170.202(a).

(2) Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012, IBR approved for § 170.202(e).

(q) * * *

(6) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release, IBR approved for § 170.207(a).

(7) RxNorm, September 8, 2015 Full Release Update, IBR approved for § 170.207(d).

■ 10. 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 any health care setting) 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 health IT 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 health IT designed for use in an ambulatory setting.

§ 170.314 [Amended]

■ 11. In § 170.314:

■ a. In paragraph (a)(3)(i)(A), remove “§ 170.207(f)” and add in its place “§ 170.207(f)(1)”;

■ b. In paragraph (a)(3)(i)(B), remove “§ 170.207(g)” and add in its place “§ 170.207(g)(1)”;

■ c. In paragraph (a)(8)(iii)(B)(2), remove “paragraph (b)(1)(iii)” and add in its place “paragraph (b)(1)(iii)(B) or (b)(9)(ii)(D)”;

■ d. In paragraphs (b)(2)(i) introductory text, (b)(7) introductory text, (b)(8)(iii) introductory text, (e)(1)(i)(A)(1), and (e)(2)(iii)(A), remove the term “Common MU Data Set” and add in its place “Common Clinical Data Set”;

■ e. In paragraph (c)(1)(ii), remove “§ 170.205(h)” and add in its place “§ 170.205(h)(1)”;

■ f. In paragraph (c)(2)(i), remove “§ 170.205(h)” and add in its place “§ 170.205(h)(1)”;

■ g. In paragraph (c)(3)(i), remove “§ 170.205(h)” and add in its place “§ 170.205(h)(1)”;

■ h. In paragraph (c)(3)(i), remove “(k)” and add in its place “§ (k)(1)”;

■ i. In paragraphs (d)(8)(i) and (ii), remove “§ 170.210(c)” and add in its place “170.210(c)(1)”;

■ j. In paragraph (e)(1)(i)(A) introductory text, remove “§ 170.204(a)” and add in its place “§ 170.204(a)(1)”;

■ k. In paragraph (f)(6)(i), remove “§ 170.205(i)” and add in its place “§ 170.205(i)(1)”;

■ l. In paragraphs (b)(1)(i)(A) and (B), (b)(2)(ii)(A) and (B), (b)(8)(i)(A) and (B), (e)(1)(i)(C)(1)(i) and (ii), (e)(1)(i)(C)(2)(i) and (ii), and (h)(1) and (2), remove “§ 170.202(a)” and add in its place “§ 170.202(a)(1)”.

■ 12. Add § 170.315 to subpart C to read as follows:

§ 170.315 2015 Edition health IT certification criteria.

The Secretary adopts the following certification criteria for health IT. Health IT must be able to electronically perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Clinical*—(1) *Computerized provider order entry—medications*. (i) Enable a user to record, change, and access medication orders.

(ii) *Optional*. Include a “reason for order” field.

(2) *Computerized provider order entry—laboratory*. (i) Enable a user to record, change, and access laboratory orders.

(ii) *Optional*. Include a “reason for order” field.

(3) *Computerized provider order entry—diagnostic imaging*. (i) Enable a user to record, change, and access diagnostic imaging orders.

(ii) *Optional*. Include a “reason for order” field.

(4) *Drug-drug, drug-allergy interaction checks for CPOE*—(i) *Interventions*.

Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically 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 in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(5) *Demographics*. (i) Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth.

(A) *Race and ethnicity*. (1) Enable each one of a patient’s races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.

(2) Enable each one of a patient’s ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.

(3) Aggregate each one of the patient’s races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).

(B) *Preferred language*. 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.

(C) *Sex*. Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).

(D) *Sexual orientation*. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.

(E) *Gender identity*. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.

(ii) *Inpatient setting only*. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

(6) *Problem list*. Enable a user to record, change, and access a patient’s active problem list:

(i) *Ambulatory setting only*. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

(ii) *Inpatient setting only*. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

(7) *Medication list*. Enable a user to record, change, and access a patient’s active medication list as well as medication history:

(i) *Ambulatory setting only*. Over multiple encounters.

(ii) *Inpatient setting only*. For the duration of an entire hospitalization.

(8) *Medication allergy list.* Enable a user to record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) *Ambulatory setting only.* Over multiple encounters.

(ii) *Inpatient setting only.* For the duration of an entire hospitalization.

(9) *Clinical decision support (CDS)—(i) CDS intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *CDS configuration.* (A) Enable interventions and reference resources specified in paragraphs (a)(9)(iii) and (iv) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) Enable interventions:

(1) Based on the following data:

(i) Problem list;

(ii) Medication list;

(iii) Medication allergy list;

(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;

(v) Laboratory tests; and

(vi) Vital signs.

(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(iii) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) electronic CDS interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(1)(i) through (vi) of this section.

(iv) *Linked referential CDS.* (A) Identify for a user diagnostic and therapeutic reference information in accordance at least one of the following standards and implementation specifications:

(1) The standard and implementation specifications specified in § 170.204(b)(3).

(2) The standard and implementation specifications specified in § 170.204(b)(4).

(B) For paragraph (a)(9)(iv)(A) of this section, technology must be able to 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)(9)(ii)(B)(1)(i), (ii), and (iv) of this section.

(v) *Source attributes.* Enable a user to review the attributes as indicated for all CDS resources:

(A) For evidence-based decision support interventions under paragraph (a)(9)(iii) 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 CDS in paragraph (a)(9)(iv) 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).

(10) *Drug-formulary and preferred drug list checks.* The requirements specified in one of the following paragraphs (that is, paragraphs (a)(10)(i) and (a)(10)(ii) of this section) must be met to satisfy this certification criterion:

(i) *Drug formulary checks.*

Automatically check whether a drug formulary exists for a given patient and medication.

(ii) *Preferred drug list checks.*

Automatically check whether a preferred drug list exists for a given patient and medication.

(11) *Smoking status.* Enable a user to record, change, and access the smoking status of a patient.

(12) *Family health history.* Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

(13) *Patient-specific education resources.* (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with at least one of the following standards and implementation specifications:

(A) The standard and implementation specifications specified in § 170.204(b)(3).

(B) The standard and implementation specifications specified in § 170.204(b)(4).

(ii) *Optional.* Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

(14) *Implantable device list.* (i) Record Unique Device Identifiers associated with a patient's Implantable Devices.

(ii) Parse the following identifiers from a Unique Device Identifier:

(A) Device Identifier;

(B) The following identifiers that

compose the Production Identifier:

(1) The lot or batch within which a device was manufactured;

(2) The serial number of a specific device;

(3) The expiration date of a specific device;

(4) The date a specific device was manufactured; and

(5) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

(iii) Obtain and associate with each Unique Device Identifier:

(A) A description of the implantable device referenced by at least one of the following:

(1) The "GMDN PT Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database.

(2) The "SNOMED CT® Description" mapped to the attribute referenced in paragraph (a)(14)(iii)(A)(1) of this section.

(B) The following Global Unique Device Identification Database attributes:

(1) "Brand Name";

(2) "Version or Model";

(3) "Company Name";

(4) "What MRI safety information does the labeling contain?"; and

(5) "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."

(iv) Display to a user an implantable device list consisting of:

(A) The active Unique Device Identifiers recorded for a patient; and

(B) For each active Unique Device Identifier recorded for a patient, the description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section.

(C) A method to access all Unique Device Identifiers recorded for a patient.

(v) For each Unique Device Identifier recorded for a patient, enable a user to access:

(A) The Unique Device Identifier;

(B) The description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section;

(C) The identifiers associated with the Unique Device Identifier, as specified by paragraph (a)(14)(ii) of this section;

(D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)(B) of this section.

(vi) Enable a user to change the status of a Unique Device Identifier recorded for a patient.

(15) *Social, psychological, and behavioral data.* Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

(i) *Financial resource strain*. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(p)(1) and whether a patient declines to specify financial resource strain.

(ii) *Education*. Enable education to be recorded in accordance with the standard specified in § 170.207(p)(2) and whether a patient declines to specify education.

(iii) *Stress*. Enable stress to be recorded in accordance with the standard specified in § 170.207(p)(3) and whether a patient declines to specify stress.

(iv) *Depression*. Enable depression to be recorded in accordance with the standard specified in § 170.207(p)(4) and whether a patient declines to specify depression.

(v) *Physical activity*. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(p)(5) and whether a patient declines to specify physical activity.

(vi) *Alcohol use*. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(p)(6) and whether a patient declines to specify alcohol use.

(vii) *Social connection and isolation*. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(p)(7) and whether a patient declines to specify social connection and isolation.

(viii) *Exposure to violence (intimate partner violence)*. Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

(b) *Care coordination*—(1) *Transitions of care*—(i) *Send and receive via edge protocol*—(A) Send transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) and that leads to such summaries being processed by a service that has implemented the standard specified in § 170.202(a)(2); and

(B) Receive transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a)(2).

(C) *XDM processing*. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) when the technology is also being certified using an SMTP-based edge protocol.

(ii) *Validate and display*—(A) *Validate C-CDA conformance—system*

performance. Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standards specified in § 170.205(a)(3) and § 170.205(a)(4) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(1) Parse each of the document types.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.

(ii) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and § 170.205(a)(4).

(C) *Display section views*. Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) in a manner that enables the user to:

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

(iii) *Create*. Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses*. Formatted according to at least one of the following standards:

(1) The standard specified in § 170.207(i).

(2) At a minimum, the version of the standard specified in § 170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only*. The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only*. Discharge instructions.

(G) *Patient matching data*. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:

(1) *Date of birth constraint*—(i) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(ii) *Optional*. When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(2) *Phone number constraint*. Represent phone number (home, business, cell) in accordance with the standards adopted in § 170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(3) *Sex constraint*. Represent sex in accordance with the standard adopted in § 170.207(n)(1).

(2) *Clinical information reconciliation and incorporation*—(i) *General requirements*. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates.

(ii) *Correct patient*. Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) and § 170.205(a)(4), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

(iii) *Reconciliation*. Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type:

(A) Simultaneously display (*i.e.*, in a single view) the data from at least two 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 each of the following: Medications; medication allergies; and problems.

(C) Enable a user to review and validate the accuracy of a final set of data.

(D) Upon a user's confirmation, automatically update the list, and 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)(3);

(2) *Medication allergies*. At a minimum, the version of the standard specified in § 170.207(d)(3); and

(3) *Problems*. At a minimum, the version of the standard specified in § 170.207(a)(4).

(iv) *System verification*. Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document document template.

(3) *Electronic prescribing*. (i) Enable a user to perform all of the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(2) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:

(A) Create new prescriptions (NEWRX).

(B) Change prescriptions (RXCHG, CHGRES).

(C) Cancel prescriptions (CANRX, CANRES).

(D) Refill prescriptions (REFREQ, REFRES).

(E) Receive fill status notifications (RXFILL).

(F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) For each transaction listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment.

(iii) *Optional*. For each transaction listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment.

(iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.*, not cc).

(v) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

(4) *Common Clinical Data Set summary record—create*. Enable a user to create a transition of care/referral summary formatted in accordance with

the standard specified in § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(i) The Common Clinical Data Set.

(ii) *Encounter diagnoses*. Formatted according to at least one of the following standards:

(A) The standard specified in § 170.207(i).

(B) At a minimum, the version of the standard specified in § 170.207(a)(4).

(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.

(vii) *Patient matching data*. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:

(A) *Date of birth constraint*—(1) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(2) *Optional*. When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(B) *Phone number constraint*. Represent phone number (home, business, cell) in accordance with the standards adopted in § 170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(C) *Sex constraint*. Represent sex in accordance with the standard adopted in § 170.207(n)(1).

(5) *Common Clinical Data Set summary record—receive*—(i) Enable a user to receive a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses*. Formatted according to at least one of the following standards:

(1) The standard specified in § 170.207(i).

(2) At a minimum, the standard specified in § 170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only*. The reason for referral; and referring or

transitioning provider's name and office contact information.

(F) *Inpatient setting only*. Discharge instructions.

(ii) *Validate and display*. Demonstrate the following functionalities for the document received in accordance with paragraph (b)(5)(i) of this section:

(A) *Validate C-CDA conformance—system performance*. Detect valid and invalid transition of care/referral summaries including the ability to:

(1) Parse each of the document types formatted according to the following document templates: Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.

(ii) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and § 170.205(a)(4).

(C) *Display section views*. Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) in a manner that enables the user to:

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

(6) *Data export*—(i) *General requirements for export summary configuration*. (A) Enable a user to set the configuration options specified in paragraph (b)(6)(ii) through (v) of this section when creating an export summary as well as a set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses

and without subsequent developer assistance to operate.

(B) Limit the ability of users who can create export summaries in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(ii) *Creation configuration*. Enable a user to configure the technology to create export summaries formatted in accordance with the standard specified in § 170.205(a)(4) using the Continuity of Care Document document template that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses*. Formatted according to at least one of the following standards:

(1) The standard specified in § 170.207(i).

(2) At a minimum, the version of the standard specified in § 170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only*. The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only*. Discharge instructions.

(iii) *Timeframe configuration*. (A) Enable a user to set the date and time period within which data would be used to create the export summaries. This must include the ability to enter in a start and end date and time range.

(B) Consistent with the date and time period specified in paragraph (b)(6)(iii)(A) of this section, enable a user to do each of the following:

(1) Create export summaries in real-time;

(2) Create export summaries based on a relative date and time (e.g., the first of every month at 1:00 a.m.); and

(3) Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00 a.m.).

(iv) *Location configuration*. Enable a user to set the storage location to which the export summary or export summaries are intended to be saved.

(7) *Data segmentation for privacy—send*. Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) that is document-level tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

(8) *Data segmentation for privacy—receive*. Enable a user to:

(i) Receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) that is document-level tagged as restricted and subject to restrictions on re-

disclosure according to the standard adopted in § 170.205(o)(1);

(ii) Sequester the document-level tagged document from other documents received; and

(iii) View the restricted document without incorporating any of the data from the document.

(9) *Care plan*. Enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified in § 170.205(a)(4).

(c) *Clinical quality measures—(1)*

Clinical quality measures—record and export—(i) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data 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*. A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:

(A) Formatted in accordance with the standard specified in § 170.205(h)(2);

(B) Ranging from one to multiple patients; and

(C) That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.

(2) *Clinical quality measures—import and calculate—(i) Import*. Enable a user to import a data file in accordance with the standard specified in § 170.205(h)(2) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) Calculate each and every clinical quality measure for which it is presented for certification.

(3) *Clinical quality measures—report*. Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) At a minimum, in accordance with the standards specified in § 170.205(h)(2) and § 170.205(k)(1) and (2).

(ii) *Optional*. That can be electronically accepted by CMS.

(4) *Clinical quality measures—filter*.

(i) Record the data listed in paragraph (c)(4)(iii) of this section in accordance

with the identified standards, where specified.

(ii) Filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section and be able to:

(A) Create a data file of the filtered data in accordance with the standards adopted in § 170.205(h)(2) and § 170.205(k)(1) and (2); and

(B) Display the filtered data results in human readable format.

(iii) *Data*.

(A) Taxpayer Identification Number.

(B) National Provider Identifier.

(C) Provider type in accordance with, at a minimum, the standard specified in § 170.207(r)(1).

(D) Practice site address.

(E) Patient insurance in accordance with, at a minimum, the standard specified in § 170.207(s)(1).

(F) Patient age.

(G) Patient sex in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(1).

(H) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2).

(I) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

(d) *Privacy and security—(1) Authentication, access control, and authorization*. (i) Verify against a unique identifier(s) (e.g., username or number) that a user 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 technology.

(2) *Auditable events and tamper-resistance—(i) Record actions*.

Technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and

(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by technology in accordance with the standard specified in § 170.210(e)(3) unless the technology prevents electronic health information from being locally stored on end-user

devices (see paragraph (d)(7) of this section).

(ii) *Default setting.* Technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) and (d)(2)(i)(C) of this section.

(iii) *When disabling the audit log is permitted.* For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.

(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 technology.

(v) *Detection.* 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 in § 170.210(e).

(4) *Amendments.* Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (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 in at least one of the following ways:

(A) To the affected record.

(B) Include a link that indicates this information's location.

(5) *Automatic access time-out.* (i) Automatically stop user access to health information after a predetermined period of inactivity.

(ii) Require user authentication in order to resume or regain the access that was stopped.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* The requirements specified in one of the following paragraphs (that is, paragraphs (d)(7)(i) and (d)(7)(ii) of this section) must be met to satisfy this certification criterion.

(i) 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 the 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)(2).

(B) *Default setting.* 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) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in § 170.210(c)(2).

(ii) Verify in accordance with the standard specified in § 170.210(c)(2) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Trusted connection.* Establish a trusted connection using one of the following methods:

(i) *Message-level.* Encrypt and integrity protect message contents in accordance with the standards specified in § 170.210(a)(2) and (c)(2).

(ii) *Transport-level.* Use a trusted connection in accordance with the standards specified in § 170.210(a)(2) and (c)(2).

(10) *Auditing actions on health information.* (i) By default, be set to record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1).

(ii) If technology permits auditing to be disabled, the ability to do so must be restricted to a limited set of users.

(iii) Actions recorded related to electronic health information must not be capable of being changed, overwritten, or deleted by the technology.

(iv) Technology must be able to detect whether the audit log has been altered.

(11) *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 internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in

accordance with the standard specified in § 170.204(a)(2).

(A) *View.* Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

(1) The Common Clinical 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.

(4) *Laboratory test report(s).* Laboratory test report(s), including:

(i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

(ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(5) Diagnostic image report(s).

(B) *Download.* (1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(i) Human readable format; and

(ii) The format specified in accordance to the standard specified in § 170.205(a)(4) following the CCD document template.

(2) When downloaded according to the standard specified in § 170.205(a)(4) following the CCD document template, 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), (2), (4), and (5) of this section.

(ii) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5) of this section.

(3) *Inpatient setting only.* Patients (and their authorized representatives) must be able to 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 specified in paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with both of the following ways:

(i) Email transmission to any email address; and

(ii) An encrypted method of electronic transmission.

(2) *Inpatient setting only.* Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by (e)(1)(i)(B)(3)) of this section selected by the patient (or their authorized representative) in both of the ways referenced (e)(1)(i)(C)(1)(i) and (ii) of this section).

(D) *Timeframe selection.* With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A), (B), and (C) of this section, patients (and their authorized representatives) must be able to:

(1) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

(2) Select data within an identified date range (to be viewed, downloaded, or transmitted).

(ii) *Activity history log.* (A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section are used, 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 in § 170.210(g);

(3) The user who took the action; and

(4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) 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 specified in § 170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) of this section is accessible by the patient.

(2) *Secure messaging.* Enable a user to send messages to, and receive messages from, a patient in a secure manner.

(3) *Patient health information capture.* Enable a user to:

(i) Identify, record, and access information directly and electronically shared by a patient (or authorized representative).

(ii) Reference and link to patient health information documents.

(f) *Public health—(1) Transmission to immunization registries.* (i) Create immunization information for electronic transmission in accordance with:

(A) The standard and applicable implementation specifications specified in § 170.205(e)(4).

(B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines.

(C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.

(ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

(2) *Transmission to public health agencies—syndromic surveillance.* Create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(3) *Transmission to public health agencies—reportable laboratory tests and values/results.* 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).

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(4) *Transmission to cancer registries.* Create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2).

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

(5) *Transmission to public health agencies—electronic case reporting.* (i) Consume and maintain a table of trigger codes to determine which encounters may be reportable.

(ii) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.

(iii) *Case report creation.* Create a case report for electronic transmission:

(A) Based on a matched trigger from paragraph (f)(5)(ii).

(B) That includes, at a minimum:

(1) The Common Clinical Data Set.

(2) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(i) The standard specified in § 170.207(i).

(ii) At a minimum, the version of the standard specified in § 170.207(a)(4).

(3) The provider's name, office contact information, and reason for visit.

(4) An identifier representing the row and version of the trigger table that triggered the case report.

(6) *Transmission to public health agencies—antimicrobial use and resistance reporting.* Create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).

(7) *Transmission to public health agencies—health care surveys.* Create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).

(g) *Design and performance—(1) Automated numerator recording.* For each EHR Incentive Programs percentage-based measure, 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 EHR Incentive Programs percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure.

(3) *Safety-enhanced design.* (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: Paragraphs (a)(1) through (9) and (14), (b)(2) and (3) of this section.

(ii) *Number of test participants.* A minimum of 10 test participants must be used for the testing of each capability identified in paragraph (g)(3)(i) of this section.

(iii) One of the following must be submitted on the user-centered design processed used:

(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard.

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

(iv) The following information/sections from NISTIR 7742 must be submitted for each capability to which

user-centered design processes were applied:

(A) Name and product version; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: Sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) The specific metrics captured during the testing of each user task performed in (g)(3)(iv)(C) of this section, which must include: Task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy) or an alternative acceptable user satisfaction measure;

(E) Test results for each task using the metrics identified above in paragraph (g)(3)(iv)(D) of this section; and

(F) Results and data analysis narrative, including: Major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(v) Submit test scenarios used in summative usability testing.

(4) *Quality management system.* (i) For each capability that a 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 that satisfies one of the following ways:

(A) The QMS used is established by the Federal government or a standards developing organization.

(B) The QMS used is mapped to one or more QMS established by the Federal government or standards developing organization(s).

(ii) When a single QMS was used for applicable capabilities, it would only need to be identified once.

(iii) When different QMS were applied to specific capabilities, each QMS applied would need to be identified.

(5) *Accessibility-centered design.* For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) When a single accessibility-centered design standard or law was

used for applicable capabilities, it would only need to be identified once.

(ii) When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

(6) *Consolidated CDA creation performance.* The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iv) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially. This certification criterion's scope includes only data expressed within the Common Clinical Data Set definition.

(i) *Reference C-CDA match.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.

(ii) *Document-template conformance.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought. The scope of this certification criterion will not exceed the evaluation of the CCD, Referral Note, and Discharge Summary document templates.

(iii) *Vocabulary conformance.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

(iv) *Completeness verification.* Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in the Common Clinical Data Set definition.

(7) *Application access—patient selection.* The following technical outcome and conditions must be met through the demonstration of an application programming interface (API).

(i) *Functional requirement.* The technology must be able to receive a request with sufficient information to uniquely identify a patient and return

an ID or other token that can be used by an application to subsequently execute requests for that patient's data.

(ii) *Documentation—(A)* The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(7)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(8) *Application access—data category request.* The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) *Functional requirements.* (A) Respond to requests for patient data (based on an ID or other token) for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in a computable format.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) *Documentation—(A)* The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(8)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(9) *Application access—all data request.* The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) *Functional requirements.* (A) Respond to requests for patient data (based on an ID or other token) for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard specified in § 170.205(a)(4) following the CCD document template.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) *Documentation*—(A) The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(9)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(h) *Transport methods and other protocols*—(1) *Direct Project*—(i) *Applicability Statement for Secure Health Transport.* Able to send and receive health information in accordance with the standard specified in § 170.202(a)(2), including formatted only as a “wrapped” message.

(ii) *Applicability Statement for Secure Health Transport and Delivery Notification in Direct.* Able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

(2) *Direct Project, Edge Protocol, and XDR/XDM*—(i) Able to send and receive health information in accordance with:

(A) The standard specified in § 170.202(a)(2), including formatted only as a “wrapped” message;

(B) The standard specified in § 170.202(b), including support for both limited and full XDS metadata profiles; and

(C) Both edge protocol methods specified by the standard in § 170.202(d).

(ii) *Applicability Statement for Secure Health Transport and Delivery Notification in Direct.* Able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

§§ 170.500, 170.501, 170.502, 170.503, 170.504, 170.505, 170.510, 170.520, 170.523, 170.525, 170.530, 170.535, 170.540, 170.545, 170.550, 170.553, 170.555, 170.557, 170.560, 170.565, 170.570, 170.575, and 170.599 [Amended]

■ 13. In subpart E, consisting of §§ 170.500 through 170.599:

■ a. Remove the term “ONC HIT Certification Program” and add in its place “ONC Health IT Certification Program” wherever it may appear;

■ b. Remove the acronym “HIT” and add in its place “health IT” wherever it may appear;

■ c. Remove the term “EHR Module” and add in its place “Health IT Module” wherever it may appear;

■ d. Remove the term “EHR Modules” and add in its place “Health IT Modules” wherever it may appear; and

■ e. Remove the term “EHR Module(s)” and add in its place “Health IT Module(s)” wherever it may appear.

■ 14. In § 170.503, revise paragraph (e)(4) to read as follows:

§ 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

* * * * *

(e) * * *

(4) Verify that ONC-ACBs are performing surveillance as required by and in accordance with § 170.556, § 170.523(k), and their respective annual plans; and

* * * * *

■ 15. Amend § 170.523 by—

■ a. Revising paragraphs (f), (g), (i), and (k); and

■ b. Adding paragraphs (m) and (n).

The additions and revisions read as follows:

§ 170.523 Principles of proper conduct for ONC-ACBs.

* * * * *

(f) Provide ONC, no less frequently than weekly, a current list of Health IT Modules, Complete EHRs, and/or EHR Modules that have been certified that includes, at a minimum:

(1) For the 2015 Edition health IT certification criteria and subsequent editions of health IT certification criteria:

(i) The Health IT Module developer name; product name; product version; developer Web site, physical address,

email, phone number, and contact name;

(ii) The ONC-ACB Web site, physical address, email, phone number, and contact name, contact function/title;

(iii) The ATL Web site, physical address, email, phone number, and contact name, contact function/title;

(iv) Location and means by which the testing was conducted (e.g., remotely with health IT developer at its headquarters location);

(v) The date(s) the Health IT Module was tested;

(vi) The date the Health IT Module was certified;

(vii) The unique certification number or other specific product identification;

(viii) The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test data versions used, test tool version used, and whether any test data was altered (i.e., a yes/no) and for what purpose;

(ix) The way in which each privacy and security criterion was addressed for the purposes of certification;

(x) The standard or mapping used to meet the quality management system certification criterion;

(xi) The standard(s) or lack thereof used to meet the accessibility-centered design certification criterion;

(xii) *Where applicable*, the hyperlink to access an application programming interface (API)’s documentation and terms of use;

(xiii) *Where applicable*, which certification criteria were gap certified;

(xiv) *Where applicable*, if a certification issued was a result of an inherited certified status request;

(xv) *Where applicable*, the clinical quality measures to which the Health IT Module has been certified;

(xvi) *Where applicable*, any additional software a Health IT Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary;

(xvii) *Where applicable*, the standard(s) used to meet a certification criterion where more than one is permitted;

(xviii) *Where applicable*, any optional capabilities within a certification criterion to which the Health IT Module was tested and certified;

(xix) *Where applicable*, and for each applicable certification criterion, all of the information required to be submitted by Health IT Module developers to meet the safety-enhanced design certification criterion. Each user-centered design element required to be reported must be at a granular level (e.g., task success/failure);

(xx) A hyperlink to the disclosures required by § 170.523(k)(1) for the Health IT Module;

(xxi) The attestation required by § 170.523(k)(2);

(xxii) *When applicable*, for each instance in which a Health IT Module failed to conform to its certification and for which corrective action was instituted under § 170.556 (provided no provider or practice site is identified):

(A) The specific certification requirements to which the technology failed to conform, as determined by the ONC-ACB;

(B) A summary of the deficiency or deficiencies identified by the ONC-ACB as the basis for its determination of non-conformity;

(C) When available, the health IT developer's explanation of the deficiency or deficiencies;

(D) The dates surveillance was initiated and completed;

(E) The results of randomized surveillance, including pass rate for each criterion in instances where the Health IT Module is evaluated at more than one location;

(F) The number of sites that were used in randomized surveillance;

(G) The date of the ONC-ACB's determination of non-conformity;

(H) The date on which the ONC-ACB approved a corrective action plan;

(I) The date corrective action began (effective date of approved corrective action plan);

(J) The date by which corrective action must be completed (as specified by the approved corrective action plan);

(K) The date corrective action was completed; and

(L) A description of the resolution of the non-conformity or non-conformities.

(2) For the 2014 Edition EHR certification criteria:

(i) The Complete EHR or EHR Module developer name (if applicable);

(ii) The date certified;

(iii) The product version;

(iv) The unique certification number or other specific product identification;

(v) The clinical quality measures to which a Complete EHR or EHR Module has been certified;

(vi) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary;

(vii) Where applicable, the certification criterion or criteria to which each EHR Module has been certified; and

(viii) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

(ix) A hyperlink to the disclosures required by § 170.523(k)(1) for the Complete EHRs and/or EHR Modules; and

(x) The attestation required by § 170.523(k)(2); and

(xi) *When applicable*, for each instance in which a Complete EHR or EHR Module failed to conform to its certification and for which corrective action was instituted under § 170.556 (provided no provider or practice site is identified):

(A) The specific certification requirements to which the technology failed to conform, as determined by the ONC-ACB;

(B) A summary of the deficiency or deficiencies identified by the ONC-ACB as the basis for its determination of non-conformity;

(C) When available, the health IT developer's explanation of the deficiency or deficiencies;

(D) The dates surveillance was initiated and completed;

(E) The results of randomized surveillance, including pass rate for each criterion in instances where the Complete EHR or EHR Module is evaluated at more than one location;

(F) The number of sites that were used in randomized surveillance;

(G) The date of the ONC-ACB's determination of non-conformity;

(H) The date on which the ONC-ACB approved a corrective action plan;

(I) The date corrective action began (effective date of approved corrective action plan);

(J) The date by which corrective action must be completed (as specified by the approved corrective action plan);

(K) The date corrective action was completed; and

(L) A description of the resolution of the non-conformity or non-conformities.

(g) *Records retention.* (1) Retain all records related to the certification of Complete EHRs and Health IT Modules to an edition of certification criteria for a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (g)(1) of this section;

* * * * *

(i) *Surveillance plan.* Submit an annual surveillance plan to the National Coordinator and, in accordance with its surveillance plan, its accreditation, and § 170.556:

(1) Conduct surveillance of certified Complete EHRs and Health IT Modules; and

(2) Report, at a minimum, on a quarterly basis to the National Coordinator the results of its surveillance.

* * * * *

(k) Ensure adherence to the following requirements when issuing any certification and during surveillance of Complete EHRs and Health IT Modules the ONC-ACB has certified.

(1) *Mandatory disclosures.* A Health IT developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or Health IT Module's certification:

(i) The disclaimer "This [Complete EHR or Health IT Module] is [specify Edition of EHR certification criteria] compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services."

(ii) The following information an ONC-ACB is required to report to the National Coordinator:

(A) For a Health IT Module certified to 2015 Edition health IT certification criteria, the information specified by paragraphs (f)(1)(i), (vi), (vii), (viii), (xvi), and (xvii) of this section as applicable for the specific Health IT Module.

(B) For a Complete EHR or EHR Module certified to 2014 Edition health IT certification criteria, the information specified by paragraphs (f)(2)(i), (ii), (iv)-(v), and (vii) of this section as applicable for the specific Complete EHR or EHR Module.

(iii) In plain language, a detailed description of all known material information concerning:

(A) Additional types of costs that a user may be required to pay to implement or use the Complete EHR or Health IT Module's capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification.

(B) Limitations that a user may encounter in the course of implementing and using the Complete EHR or Health IT Module's capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification.

(iv) The types of information required to be disclosed under paragraph (k)(iii) of this section include but are not limited to:

(A) Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

(B) Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified.

(C) Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

(v) Health IT self-developers are excluded from the requirements of paragraph (k)(1)(iii) of this section.

(2) *Transparency attestation.* As a condition of a Complete EHR or Health IT Module's certification to any certification criterion, a health IT developer must make one of the following attestations:

(i) An attestation that it will voluntarily and timely provide, in plain writing and in a manner calculated to inform, any part (including all of) the information required to be disclosed under paragraph (k)(1) of this section, (A) to all customers, prior to providing or entering into any agreement to provide any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services during the course of an on-going agreement);

(B) to any person who requests or receives a quotation, estimate, description of services, or other assertion or information from the developer in connection with any certified health IT or any capabilities thereof; and

(C) to any person, upon request.

(ii) An attestation by the developer that it has been asked to make the voluntary transparency attestation described by paragraph (k)(2)(i) of this section and has elected not to make such attestation.

(3) A certification issued to a pre-coordinated, integrated bundle of Health IT Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section, except that the certification must also indicate each Health IT Module that is included in the bundle; and

(4) A certification issued to a Complete EHR or Health IT Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

* * * * *

(m) *Adaptations and updates.* On a quarterly basis each calendar year, obtain a record of:

(1) All adaptations of certified Complete EHRs and certified Health IT Modules; and

(2) All updates made to certified Complete EHRs and certified Health IT Modules affecting the capabilities in certification criteria to which the "safety-enhanced design" criteria apply.

(n) *Complaints reporting.* Submit a list of complaints received to the National Coordinator on a quarterly basis each calendar year that includes the number of complaints received, the nature/substance of each complaint, and the type of complainant for each complaint.

■ 16. Amend § 170.550 by—

■ a. Redesignating paragraph (g) as paragraph (k);

■ b. Adding paragraphs (g), (h) and (j); and

■ c. Adding reserved paragraph (i).

The additions read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(g) When certifying a Health IT Module to the 2015 Edition health IT certification criteria, an ONC-ACB must certify the Health IT Module in accordance with the certification criteria at:

(1) Section 170.315(g)(3) if the Health IT Module is presented for certification to one or more listed certification criteria in § 170.315(g)(3);

(2) Section 170.315(g)(4);

(3) Section 170.315(g)(5); and

(4) Section 170.315(g)(6) if the Health IT Module is presented for certification with C-CDA creation capabilities within

its scope. If the scope of certification sought includes multiple certification criteria that require C-CDA creation, § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each. If the scope of certification sought includes multiple certification criteria that require C-CDA creation, § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each so long as all applicable C-CDA document templates have been evaluated as part of § 170.315(g)(6) for the scope of the certification sought.

(h) *Privacy and security certification framework—(1) General rule.* When certifying a Health IT Module to the 2015 Edition health IT certification criteria, an ONC-ACB can only issue a certification to a Health IT Module if the privacy and security certification criteria in paragraphs (h)(3)(i) through (viii) of this section have also been met (and are included within the scope of the certification).

(2) In order to be issued a certification, a Health IT Module would only need to be tested once to each applicable privacy and security criterion in paragraphs (h)(3)(i) through (viii) of this section so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification, except for the following:

(i) A Health IT Module presented for certification to § 170.315(e)(1) must be separately tested to § 170.315(d)(9); and

(ii) A Health IT Module presented for certification to § 170.315(e)(2) must be separately tested to § 170.315(d)(9).

(3) *Applicability.* (i) Section 170.315(a) is also certified to the certification criteria specified in § 170.315(d)(1) through (7);

(ii) Section 170.315(b) is also certified to the certification criteria specified in § 170.315(d)(1) through (3) and (d)(5) through (8);

(iii) Section 170.315(c) is also certified to the certification criteria specified in § 170.315(d)(1) through (3), and (5);

(iv) Section 170.315(e)(1) is also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5), (7), and (9);

(v) Section 170.315(e)(2) and (3) is also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5), and (9);

(vi) Section 170.315(f) is also certified to the certification criteria specified in § 170.315(d)(1) through (3) and (7);

(vii) Section 170.315(g)(7), (8) and (9) is also certified to the certification criteria specified in § 170.315(d)(1) and (9); and (d)(2) or (10);

(viii) Section 170.315(h) is also certified to the certification criteria specified in § 170.315(d)(1) through (3); and

(4) *Methods to demonstrate compliance with each privacy and security criterion.* One of the following methods must be used to meet each applicable privacy and security criterion listed in paragraph (h)(3) of this section:

(i) Directly, by demonstrating a technical capability to satisfy the applicable certification criterion or certification criteria; or

(ii) Demonstrate, through system documentation sufficiently detailed to enable integration, that the Health IT Module has implemented service interfaces for each applicable privacy and security certification criterion that enable the Health IT Module to access external services necessary to meet the privacy and security certification criterion.

(j) [Reserved]

(j) *Direct Project transport method.* An ONC-ACB can only issue a certification to a Health IT Module for § 170.315(h)(1) if the Health IT Module's certification also includes § 170.315(b)(1).

* * * * *

§ 170.553 [Removed and Reserved]

■ 17. Remove and reserve § 170.553.

■ 18. Add § 170.556 to read as follows:

§ 170.556 In-the-field surveillance and maintenance of certification for Health IT.

(a) *In-the-field surveillance.* Consistent with its accreditation to ISO/IEC 17065 and the requirements of this subpart, an ONC-ACB must initiate surveillance "in the field" as necessary to assess whether a certified Complete EHR or certified Health IT Module continues to conform to the requirements of its certification once the certified Complete EHR or certified Health IT Module has been implemented and is in use in a production environment.

(1) *Production environment.* An ONC-ACB's assessment of a certified capability in the field must be based on the use of the capability in a production environment, which means a live environment in which the capability has been implemented and is in use.

(2) *Production data.* An ONC-ACB's assessment of a certified capability in the field must be based on the use of the capability with production data unless the use of test data is specifically approved by the National Coordinator.

(b) *Reactive surveillance.* An ONC-ACB must initiate surveillance (including, as necessary, in-the-field surveillance required by paragraph (a) of this section) whenever it becomes aware of facts or circumstances that would cause a reasonable person to question a certified Complete EHR or certified Health IT Module's continued conformity to the requirements of its certification.

(1) *Review of required disclosures.* When an ONC-ACB performs reactive surveillance under this paragraph, it must verify that the requirements of § 170.523(k)(1) have been followed as applicable to the issued certification.

(2) [Reserved]

(c) *Randomized surveillance.* During each calendar year surveillance period, an ONC-ACB must conduct in-the-field surveillance for certain randomly selected Complete EHRs and Health IT Modules to which it has issued a certification.

(1) *Scope.* When an ONC-ACB selects a certified Complete EHR or certified Health IT Module for randomized surveillance under this paragraph, its evaluation of the certified Complete EHR or certified Health IT Module must include all certification criteria prioritized by the National Coordinator that are part of the scope of the certification issued to the Complete EHR or Health IT Module.

(2) *Minimum number of products selected per year.* 2% of the Complete EHRs and Health IT Modules to which an ONC-ACB has issued a certification must be subject to randomized surveillance.

(3) *Selection method.* An ONC-ACB must randomly select (subject to appropriate weighting and sampling considerations) certified Complete EHRs and certified Health IT Modules for surveillance under this paragraph.

(4) *Number and types of locations for in-the-field surveillance.* For each certified Complete EHR or certified Health IT Module selected for randomized surveillance under this paragraph, an ONC-ACB must:

(i) Evaluate the certified Complete EHR or certified Health IT Module's capabilities at one or more locations where the certified Complete EHR or certified Health IT Module is implemented and is in use in the field.

(ii) Ensure that the locations are selected at random (subject to appropriate weighting and sampling considerations) from among all locations where the certified Complete EHR or certified Health IT Module is implemented and is in use in the field.

(5) *Exclusion and exhaustion.* An ONC-ACB must make a good faith effort

to complete in-the-field surveillance of a certified Complete EHR or certified Health IT Module at each location selected under paragraph (c)(3) of this section. If the ONC-ACB is unable to complete surveillance at a location due to circumstances beyond its control, the ONC-ACB may substitute a different location that meets the requirements of paragraph (c)(3) of this section. If no such location exists, the ONC-ACB may exclude the certified Complete EHR or certified Health IT Module and substitute a different randomly selected Complete EHR or Health IT Module to which it has issued a certification.

(6) *Prohibition on consecutive selection for randomized surveillance.* An ONC-ACB is prohibited from selecting a certified Complete EHR or certified Health IT Module for randomized surveillance under this paragraph more than once during any consecutive 12 month period. This limitation does not apply to reactive and other forms of surveillance required under this subpart and the ONC-ACB's accreditation.

(d) *Corrective action plan and procedures.* (1) When an ONC-ACB determines, through surveillance under this section or otherwise, that a Complete EHR or Health IT Module does not conform to the requirements of its certification, the ONC-ACB must notify the developer of its findings and require the developer to submit a proposed corrective action plan for the applicable certification criterion, certification criteria, or certification requirement.

(2) The ONC-ACB shall provide direction to the developer as to the required elements of the corrective action plan.

(3) The ONC-ACB shall verify the required elements of the corrective action plan, consistent with its accreditation and any elements specified by the National Coordinator. At a minimum, any corrective action plan submitted by a developer to an ONC-ACB must include:

(i) A description of the identified non-conformities or deficiencies;

(ii) An assessment of how widespread or isolated the identified non-conformities or deficiencies may be across all of the developer's customers and users of the certified Complete EHR or certified Health IT Module;

(iii) How the developer will address the identified non-conformities or deficiencies, both at the locations under which surveillance occurred and for all other potentially affected customers and users;

(iv) How the developer will ensure that all affected and potentially affected

customers and users are alerted to the identified non-conformities or deficiencies, including a detailed description of how the developer will assess the scope and impact of the problem, including identifying all potentially affected customers; how the developer will promptly ensure that all potentially affected customers are notified of the problem and plan for resolution; how and when the developer will resolve issues for individual affected customers; and how the developer will ensure that all issues are in fact resolved.

(v) The timeframe under which corrective action will be completed.

(vi) An attestation by the developer that it has completed all elements of the approved corrective action plan.

(4) When the ONC-ACB receives a proposed corrective action plan (or a revised proposed corrective action plan), the ONC-ACB shall either approve the corrective action plan or, if the plan does not adequately address the elements described by paragraph (d)(3) of this section and other elements required by the ONC-ACB, instruct the developer to submit a revised proposed corrective action plan.

(5) *Suspension.* Consistent with its accreditation to ISO/IEC 17065 and procedures for suspending a certification, an ONC-ACB shall initiate suspension procedures for a Complete EHR or Health IT Module:

(i) 30 days after notifying the developer of a non-conformity pursuant to paragraph (d)(1) of this section, if the developer has not submitted a proposed corrective action plan;

(ii) 90 days after notifying the developer of a non-conformity pursuant to paragraph (d)(1) of this section, if the ONC-ACB cannot approve a corrective action plan because the developer has not submitted a revised proposed corrective action plan in accordance with paragraph (d)(4) of this section; and

(iii) Immediately, if the developer has not completed the corrective actions specified by an approved corrective action plan within the time specified therein.

(6) *Termination.* If a certified Complete EHR or certified Health IT Module's certification has been suspended in the context of randomized surveillance under this paragraph, an ONC-ACB is permitted to initiate certification termination procedures for the Complete EHR or Health IT Module (consistent with its accreditation to ISO/IEC 17065 and procedures for terminating a certification) when the developer has not completed the actions necessary to reinstate the suspended certification.

(e) *Reporting of surveillance results requirements—(1) Rolling submission of in-the-field surveillance results.* The results of in-the-field surveillance under this section must be submitted to the

National Coordinator on an ongoing basis throughout the calendar year.

(2) *Confidentiality of locations evaluated.* The contents of an ONC-ACB's surveillance results submitted to the National Coordinator must not include any information that would identify any user or location that participated in or was subject to surveillance.

(3) *Reporting of corrective action plans.* When a corrective action plan is initiated for a Complete EHR or Health IT Module, an ONC-ACB must report the Complete EHR or Health IT Module and associated product and corrective action information to the National Coordinator in accordance with § 170.523(f)(1)(xxii) or (f)(2)(xi), as applicable.

(f) *Relationship to other surveillance requirements.* Nothing in this section shall be construed to limit or constrain an ONC-ACB's duty or ability to perform surveillance, including in-the-field surveillance, or to suspend or terminate the certification, of any certified Complete EHR or certified Health IT Module as required or permitted by this subpart and the ONC-ACB's accreditation to ISO/IEC 17065.

Dated: September 25, 2015.

Sylvia M. Burwell,
Secretary.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 495

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 495

[CMS–3310–FC and CMS–3311–FC]

RINs 0938–AS26 and 0938–AS58

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017

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

ACTION: Final rules with comment period.

SUMMARY: This final rule with comment period specifies the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. In addition, it changes the Medicare and Medicaid EHR Incentive Programs reporting period in 2015 to a 90-day period aligned with the calendar year. This final rule with comment period also removes reporting requirements on measures that have become redundant, duplicative, or topped out from the Medicare and Medicaid EHR Incentive Programs. In addition, this final rule with comment period establishes the requirements for Stage 3 of the program as optional in 2017 and required for all participants beginning in 2018. The final rule with comment period continues to encourage the electronic submission of clinical quality measure (CQM) data, establishes requirements to transition the program to a single stage, and aligns reporting for providers in the Medicare and Medicaid EHR Incentive Programs.

DATES: *Effective Date:* These regulations are effective on December 15, 2015.

Comment Date: To be assured consideration, comments on sections II.B.1.b.(3).(iii), II.B.1.b.(4).(a), II.B.2.b, II.D.1.e, and II.G.2 of preamble to this final rule with comment period; paragraphs (1)(ii)(C)(3), (1)(iii), (2)(ii)(C)(3) and 2(iii) of the definition of an EHR reporting period at § 495.4; and paragraphs (2)(ii)(C)(2) and (2)(iii) of the definition of an EHR reporting period for a payment adjustment year at § 495.4 must be received at one of the addresses provided in the **ADDRESSES** section no

later than 5 p.m. EST on December 15, 2015.

ADDRESSES: In commenting, please refer to file code CMS–3310 & 3311–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.

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–3310 & 3311–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

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

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3310 & 3311–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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

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

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

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

Comments mailed to the addresses indicated as appropriate for hand or

courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Holland, (410) 786–1309, Medicare EHR Incentive Program and Medicare payment adjustment.
Elisabeth Myers (CMS), (410) 786–4751, Medicare EHR Incentive Program.
Thomas Romano (CMS), (410) 786–0465, Medicaid EHR Incentive Program.
Ed Howard (CMS), (410) 786–6368, Medicare Advantage.
Elise Sweeney Anthony (ONC), (202) 475–2485, Certification definition.

SUPPLEMENTARY INFORMATION:

Electronic Access

Inspection of Public Comments: All public 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 public 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.

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at: <http://www.gpo.gov/fdsys>.

Acronyms

API Application Programming Interface
ARRA American Recovery and Reinvestment Act of 2009
ACO Accountable Care Organization
AIU Adopt, Implement, Upgrade (certified EHR Technology)
CAH Critical Access Hospital
CCD Continuity of Care Document
CCDA C–CDA, Consolidated Clinical Document Architecture
CCDS Common Clinical Data Set
CCN CMS Certification Number
CDC Centers for Disease Control & Prevention
CDR Clinical Data Registry
CDS Clinical Decision Support
CEHRT Certified Electronic Health Record Technology
CFR Code of Federal Regulations
CHIP Children’s Health Insurance Program
CHIPRA Children’s Health Insurance Program Reauthorization Act of 2009
CMS Centers for Medicare & Medicaid Services
CPCI Comprehensive Primary Care Initiative

CPOE Computerized Physician Order Entry
 CQM Clinical Quality Measure
 CY Calendar Year
 DEC Data Element Catalog
 eCQM Electronic Clinical Quality Measure
 EHR Electronic Health Record
 ELR Electronic Reportable Lab
 EP Eligible Professional
 ePHI Electronic Protected Health Information
 eRx Electronic Prescribing
 FACA Federal Advisory Committee Act
 FAQ Frequently asked question
 FCC Federal Communications Commission
 FPC Federal Financial Participation
 FFS Fee-for-Service
 FQHC Federally Qualified Health Center
 FY Fiscal Year
 HEDIS Healthcare Effectiveness Data and Information Set
 HHS Department of Health and Human Services
 HIE Health Information Exchange
 HIT Health Information Technology
 HIPAA Health Insurance Portability and Accountability Act of 1996
 HITECH Health Information Technology for Economic and Clinical Health Act
 HMO Health Maintenance Organization
 ICR Information Collection Requirement
 IFC Interim Final Rule with Comment Period
 IPPS Inpatient Prospective Payment System
 IQR Inpatient Quality Reporting
 IT Information Technology
 MA Medicare Advantage
 MACRA Medicare Access and CHIP Reauthorization Act of 2015
 MIPS Merit-Based Incentive Payment System
 MITA Medicaid Information Technology Architecture
 NPI National Provider Identifier
 NPPES National Plan and Provider Enumeration System
 NwHIN Nationwide Health Information Network
 NQF National Quality Forum
 ONC Office of the National Coordinator for Health Information Technology
 OTC Over the counter
 PFS Physician Fee Schedule
 PHA Public Health Agency
 PHSA Public Health Service Act
 POS Place of Service
 PQRS Physician Quality Reporting System
 PHI Protected Health Information
 QA Quality Assurance
 QRDA Quality Reporting Data Architecture
 SMHP State Medicaid Health Information Technology Plan
 SRA Security Risk Assessment
 ToC Transitions of Care
 VDT View, Download, and Transmit

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Regulations Text

I. Executive Summary and Background

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for Regulatory Action

This final rule with comment period addresses the proposals made in two separate CMS notices of proposed rulemaking (NPRM); the March 30, 2015 “Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3” NPRM (80 FR 16731 through 16804) (hereafter referred to as the “Stage 3 proposed rule”) and the April 9, 2015 “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017” NPRM (80 FR 20346 through 20399) (hereafter referred to as the “EHR Incentive Programs in 2015 through 2017 proposed rule”). However, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted on April 16, 2015, after publication of the

proposed EHR rule. Section 101(b)(1)(A) of MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment for EPs at the end of CY 2018. Section 101(c) of MACRA added section 1848(q) of the Act requiring the establishment of a Merit-Based Incentive Payment System (MIPS), which would incorporate meaningful use. In light of the passage of MACRA, this final rule with comment period also allows for a 60-day public comment period on certain provisions noted in the **SUPPLEMENTARY INFORMATION** section above in part to support the transition to MIPS. The comments received during the comment period may be considered as we prepare for future rulemaking to implement MIPS, which in general is expected to be more broadly focused on quality and care delivery.

The enactment of MACRA has altered the EHR Incentive Programs such that the existing Medicare payment adjustment for EPs under 1848(a)(7)(A) of the Act will end in CY 2018 and be incorporated under MIPS beginning in CY 2019. It is our intent to issue a notice of proposed rulemaking for MIPS by mid-2016. This final rule with comment period synchronizes reporting under the EHR Incentive Programs to end the separate stages of meaningful use, which we believe will prepare Medicare EPs for the transition to MIPS.

In the Stage 3 and the EHR Incentive Program in 2015 through 2017 proposed rules, and in this final rule with comment period, we have responded to public input and comments by providing for flexibility that may assist EPs in preparing for the transition to MIPS. This final rule with comment period establishes a number of key final policies in response to these concerns: A simplification of program requirements, an introduction of flexibility within certain objectives, an option to participate in Stage 3 in 2017 but not required until 2018, and an overall focus on interoperability. We have focused on leveraging health IT to support providers and reduce burdensome requirements within an evolving environment. In light of public interest and in recognition that this is an ongoing and continuous process, we are providing a 60-day public comment period on the final policies for the Stage 3 objectives and measures and the EHR reporting period for Stage 3 in 2017 and subsequent years. Public comments received may be considered as we plan for the incorporation of meaningful use into MIPS, and any policies developed would be addressed in future rulemaking.

The Stage 3 proposed rule (80 FR 16733 through 16735) described the final stage of the program, which would incorporate portions of the prior stages into Stage 3 requirements, while altering other requirements in response to CMS's progress toward policy goals, the widespread adoption of technology and clinical standards among providers, and high performance on certain objectives among providers. These proposed changes included simplifying and reducing the number of measures, and focusing the Medicare and Medicaid EHR Incentive Programs on the advanced use of EHR technology. In addition, the proposals set a path for providers to move toward aligned reporting on a single set of requirements, with the goal of moving all participants in the Medicare and Medicaid EHR Incentive Programs to a single set of requirements in 2018. The incorporation of the requirements into one stage for all providers is intended to respond to stakeholder concerns by creating simplicity in the program by focusing on the success of certain measures that are part of the meaningful use program to date, and setting a long-term, sustainable foundation based on key advanced use objectives for the Medicare and Medicaid EHR Incentive Programs.

In the EHR Incentive Programs for 2015 through 2017 proposed rule (80 FR 20346 through 20399), we proposed to make similar modifications to Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs in order to reduce reporting burden, to eliminate redundant and duplicative reporting, and to better align the objectives and measures of meaningful use with the proposed Stage 3 requirements, which would be optional in 2017 and required beginning in 2018.

In this final rule with comment period, we are finalizing the requirements for the EHR Incentive Programs for 2015 through 2017 and for 2018 and subsequent years. We note that our intent in finalizing the Stage 3 proposed rule along with the changes for 2015 through 2017 while continuing to solicit comments on certain provisions is multifold; we are creating consistency in the policies for the current program in 2015 through 2017 and for 2018 and subsequent years; and we have established a clear vision of how current participation will assist in meeting our long-term delivery system reform goals. We believe this sustained consistency in policy will support the planning and development for MIPS and the future use of EHR across a multitude of healthcare providers.

We are also finalizing changes to the EHR reporting period, timelines, and structure of the Medicare and Medicaid EHR Incentive Programs for 2015 through 2017 to better align EHR reporting periods for providers; support a flexible, clear framework to reduce provider burden; and support future sustainability of the Medicare and Medicaid EHR Incentive Programs. Overall, the requirements of the program finalized in this rule for 2015 through 2017 seek to support near-term goals for delivery system reform and lay a foundation for our broader efforts to pursue interoperability and quality initiatives focused on improving patient outcomes.

b. Legal Authority for the Regulatory Action

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to EPs, eligible hospitals, CAHs, and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of CEHRT. Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals and CAHs, respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year (FY) 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments. (There are no payment adjustments under Medicaid). (For a more detailed explanation of the statutory basis for the EHR incentive payments, see the July 28, 2010 Stage 1 final rule titled, “Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule” (75 FR 44316 through 44317).)

2. Summary of Major Provisions

a. Considerations in Defining Meaningful Use

The Stage 1 final rule established the foundation for the Medicare and Medicaid EHR Incentive Programs by establishing requirements for the electronic capture of clinical data,

including providing patients with electronic copies of their health information. We outlined Stage 1 meaningful use criteria and finalized core and menu objectives for EPs, eligible hospitals, and CAHs. (For a full discussion of Stage 1 of meaningful use, we refer readers to the Stage 1 final rule (75 FR 44313 through 44588).)

In the September 4, 2012 Stage 2 final rule (77 FR 53967 through 54162), we focused on the next goal: The exchange of essential health data among health care providers and patients to improve care coordination. We also finalized a set of clinical quality measures (CQMs) that all providers participating in any stage of the program are required to report to CMS beginning in 2014. (For a full discussion of the meaningful use objectives and measures, and the CQMs we finalized under Stage 2, we refer readers to the Stage 2 final rule at 77 FR 53967 through 54162.)

In the March 30, 2015 **Federal Register**, we published a proposed rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3” (80 FR 16731 through 16804) hereafter referred to as the “Stage 3 proposed rule”. In the April 15, 2015 **Federal Register**, we published a proposed rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017” (80 FR 20346 through 20399) hereafter referred to as the “EHR Incentive Programs in 2015 through 2017 proposed rule”. In this final rule, we are finalizing both the Stage 3 proposed rule and the EHR Incentive Programs in 2015 through 2017 proposed rule to build on the groundwork established in Stage 1 and Stage 2 and continue our Stage 2 goal of increasing interoperable health data sharing among providers. In addition, this final rule also focuses on the advanced use of EHR technology to promote improved patient outcomes and health information exchange. We are also finalizing proposals to continue improving program efficiency, effectiveness, and flexibility by making changes to the Medicare and Medicaid EHR Incentive Programs that simplify reporting requirements and reduce program complexity.

One significant change we proposed in the Stage 3 proposed rule (80 FR 16734) included establishing a single set of objectives and measures (tailored to EPs or eligible hospitals/CAHs) to meet the definition of meaningful use for Stage 3 in 2017 and subsequent years. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20351), we additionally proposed a

transitional period in 2015 through 2017 that would help move providers along a participation continuum toward the long term goals proposed under the Stage 3 proposed rule. In this final rule, we are adopting this transition toward a new, streamlined set of requirements, including an optional year for any provider who chooses to attest to the objectives and measures for Stage 3 for an EHR reporting period in 2017. We are additionally finalizing the objectives and measures that will be required for all eligible providers—regardless of prior participation in the Medicare and Medicaid EHR Incentive Programs—for an EHR reporting period in 2018 and subsequent years.

In the Stage 3 proposed rule (80 FR 16741), we outlined our proposed approach and method for measure selection that removed topped out, redundant, and duplicative measures from reporting requirements and focused on only those measures that represent the most advanced use of the functions and standards supported by CEHRT. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed adopting this approach as applicable to the current objectives and measures in use for Stage 1 and Stage 2 of the program and aligning the current objectives and measures with those identified for long-term use in the Stage 3 proposed rule. In this final rule, we adopt the approach for the Stage 3 objectives and measures, as well as the similar approach for the objectives and measures of the EHR Incentive Program in 2015 through 2017.

b. Meaningful Use Requirements, Objectives, and Measures for 2015 Through 2017

(1) EHR Reporting Period

In this final rule, we adopt changes to the EHR reporting period for the Medicare and Medicaid EHR Incentive Programs in 2015, 2016, and 2017 and finalize the changes that align reporting periods to the calendar year. We also finalize the proposal to adopt a 90-day reporting period for all providers in 2015 and new participants in 2016, and based on public comment we are finalizing a 90-day reporting period for new participants in 2017.

(2) Objectives and Measures

In the Stage 3 proposed rule (80 FR 16741), we outlined our method and approach for identifying the objectives and measures retained for Stage 3 of meaningful use beginning in 2017. We also identified those objectives and measures that are now redundant,

duplicative, or topped out, and therefore will no longer be required for the successful demonstration of meaningful use for Stage 3. For further discussion of this approach, we refer readers to section II.B.1.b.(4).(a) of this final rule with comment period.

In this final rule, we are adopting the proposed approach from the EHR Incentive Program in 2015 through 2017 proposed rule to use a similar method to identify the objectives and measures from Stages 1 and 2 of meaningful use that we believe should no longer be required for a provider to demonstrate meaningful use in 2015 through 2017 because these measures have been identified as redundant, duplicative, or topped out. We are also finalizing changes to remove the menu and core structure of Stage 1 and Stage 2 and reduce the overall number of objectives to which a provider must attest. In addition, we are finalizing changes to individual objectives and measures for Stage 2 of meaningful use as follows:

- Changing the threshold for two measures requiring patient action (the second measure for the Stage 2 Objective for Patient Electronic Access and the measure for the Stage 2 Objective for Secure Electronic Messaging).
- Consolidating all public health reporting objectives into one objective with measure options similar to the structure of the Stage 3 Public Health Reporting Objective (80 FR 16762 through 16767).
- Changing the eligible hospital electronic prescribing objective from a menu objective to a required objective with an exclusion available for eligible hospitals and CAHs in 2015 and 2016.

We are additionally finalizing the proposal to maintain the existing definitions for the objectives and measures, including the numerator and denominator calculations, the proposal to maintain certain measure specifications for 2015, and the proposal to allow exclusions for certain measures in 2015 and 2016 in order to facilitate the transition for providers already engaged in the workflows, data capture, and measure calculation for meaningful use for an EHR reporting period in 2015 and 2016. For further discussion of this approach, we refer readers to section II.B.1.b.(4).(b) of this final rule.

c. Meaningful Use Requirements, Objectives, and Measures for Stage 3 in 2017 and Subsequent Years

(1) EHR Reporting Period

In this final rule, we are adopting changes to the EHR reporting period for 2017, 2018, and subsequent years based

on the Stage 3 proposed rule (80 FR 16739) and public comments received. We are finalizing the proposal for full calendar year reporting for providers beginning in 2018 with a limited exception for Medicaid providers in their first year of demonstrating meaningful use. We are also finalizing an optional 90-day reporting period for providers demonstrating the Stage 3 requirements for an EHR reporting period in 2017. For further discussion, we refer readers to section II.B.1.b.(3) of this final rule.

(2) Objectives and Measures

The methodology outlined in the Stage 3 proposed rule at 80 FR 16741 for the selection of objectives and measures for the Medicare and Medicaid EHR Incentive Programs for Stage 3 in 2017 and subsequent years included the following:

- Review attestation data for Stages 1 and 2 of meaningful use;
- Conduct listening sessions and interviews with providers, EHR system developers, regional extension centers, and health care provider associations; and
- Review recommendations from government agencies and advisory committees focused on health care improvement, such as the Health Information Technology (HIT) Policy Committee, the National Quality Forum (NQF), and the Centers for Disease Control and Prevention (CDC).

The information we gathered from these sources focused on analyzing measure performance, implementing discrete EHR functionalities and standards, and examining objectives and measures presenting the best opportunity to improve patient outcomes and enhance provider support.

Based on this analysis and consideration of public comment received, we are finalizing a set of 8 objectives with associated measures designed to meet the following policy goals:

- Align with national health care quality improvement efforts;
- Promote interoperability and health information exchange; and
- Focus on the 3-part aim of reducing cost, improving access, and improving quality.

We intend for Stage 3 to be the final stage of the meaningful use framework, which leverages the structure identified in the Stage 1 and Stage 2 final rules, while simultaneously establishing a single set of objectives and measures designed to promote best practices and continued improvement in health outcomes in a sustainable manner.

Measures in the Stage 1 and Stage 2 final rules that included paper-based workflows, chart abstraction, or other manual actions have been removed or transitioned to an electronic format utilizing EHR functionality for Stage 3. In addition, we are finalizing the removal of topped out measures, or measures that are no longer useful in gauging performance, because these less advanced measures are now achieving widespread adoption.

d. Certified EHR Technology Requirements for the EHR Incentive Programs

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20374), we proposed no changes to the individual certification requirements for the objectives and measures of meaningful use for an EHR reporting period in 2015 through 2017 using EHR technology certified to the 2014 Edition certification criteria. In the Stage 3 proposed rule (80 FR 16767), we proposed that providers use EHR technology certified to the 2015 Edition certification criteria for an EHR reporting period in 2018. In this rule, we are finalizing that providers may continue to usher technology certified to the 2014 Edition until EHR technology certified to the 2015 Edition is required with an EHR reporting period beginning in 2018. In the Stage 3 proposed rule, we also noted our intent to allow providers to upgrade to technology certified to the 2015 Edition as soon as such technology is available if they determine that the EHR technology certified to the 2015 Edition would support and meet the requirements of the EHR Incentive Programs in 2015 through 2017. We are finalizing that providers may use EHR technology certified to the 2014 Edition for an EHR reporting period in 2015; EHR technology certified to either the 2014 Edition, the 2015 Edition, or a combination of the two in 2016 and 2017; and EHR technology certified to the 2015 Edition for an EHR reporting period in 2018 and subsequent years.

We are also finalizing a definition of CEHRT within 42 CFR 495.4 that includes the functions and standards outlined for the certification of health information technology to the 2014 and 2015 Edition certification criteria for use in the Medicare and Medicaid EHR Incentive Programs. For further discussion of the definition and use of CEHRT, we direct readers to section II.B.3 of this final rule.

e. Clinical Quality Measurement

EPs, eligible hospitals, and CAHs must report CQMs in order to meet the

requirements of the Medicare and Medicaid EHR Incentive Programs. We are committed to continuing to promote the electronic capture, calculation, and reporting of key clinical data through the use of CEHRT. We are also focused on improving alignment of reporting requirements for CMS programs that leverage EHR technology for clinical quality reporting and quality measurement to streamline reporting mechanisms for providers and increase quality data integrity.

This final rule addresses quality reporting alignment on several fronts. Our long-term vision seeks to have hospitals, clinicians, and other health care providers report through a single, aligned mechanism for multiple CMS programs. In order to facilitate continuous quality improvement, we noted in the Stage 3 proposed rule our intent to implement changes to quality reporting requirements in conjunction with the quality reporting programs through the annual Medicare payment rules, such as the Physician Fee Schedule (PFS) and the Inpatient Prospective Payment Systems (IPPS) rules. In the Stage 3 proposed rule, we proposed to continue encouraging CQM data submission through electronic submission for Medicare participants in 2017 and to require electronic submission of CQMs where feasible beginning in 2018 for Medicare providers demonstrating meaningful use. (We further discuss Medicaid CQM submission in section II.F.3 of this final rule.)

We did not propose changes to the CQM selection or reporting scheme (9 or 16 CQMs across at least 3 domains) from the CQM requirements previously established for all providers seeking to demonstrate meaningful use in the Medicare and Medicaid EHR Incentive Programs defined in earlier rulemaking (see 77 FR 54049 through 54089). In the EHR Incentive Programs in 2015 through 2017 proposed rule, for an EHR reporting period in 2015, and for providers demonstrating meaningful use for the first time in 2016 or 2017, we proposed that providers may—

- Attest to any continuous 90-day period of CQM data during the calendar year through the Medicare EHR Incentive Program registration and attestation site; or
- Electronically report CQM data using the established methods for electronic reporting.

We are finalizing these reporting periods for CQM reporting for 2015 and 2016. We are finalizing that for 2017, providers beyond their first year of meaningful use may attest to one full calendar year of CQM data or they may

electronically report their CQM data using the established methods for electronic reporting outlined in section II.C. of this final rule. In addition, we are finalizing that for an EHR reporting period in 2018, all providers are required to submit CQM data for the Medicare EHR Incentive Program using these established methods for electronic reporting. We refer readers to section II.C. of this final rule for further information on clinical quality measurement.

f. Demonstration of Meaningful Use

We are finalizing our proposal to continue our common method for meaningful use in both the Medicare and Medicaid EHR Incentive Programs of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the requirements of the Medicare and Medicaid EHR Incentive Programs. We are additionally finalizing changes to the attestation deadlines to accommodate the change to reporting based on the calendar year for eligible hospitals and CAHs beginning with an EHR reporting period in 2015, as well as the proposed change to a 90-day EHR reporting period for all providers in 2015. We are also finalizing changes to the attestation deadlines for new meaningful EHR users in 2015 and 2016 to avoid the Medicare payment adjustments in 2016 and 2017. Finally, we are adopting the alternate attestation method proposed in the EHR Incentive Program in 2015 through 2017 proposed rule for certain Medicaid providers to demonstrate meaningful use in 2015 and subsequent years to avoid Medicare payment adjustments. For further discussion, we refer readers to section II.D of this final rule.

g. Payment Adjustments and Hardship Exceptions

The HITECH statute requires Medicare payment adjustments beginning in 2015. In this final rule, we are maintaining the payment adjustment policies for EPs, eligible hospitals, and CAHs as finalized in the Stage 2 final rule (77 FR 54093 through 54113 and 54115 through 54119), except for a change to the relationship between the EHR reporting period year, the payment adjustment year, and the attestation deadlines to avoid the payment adjustment. For the discussion of payment adjustments and hardship exceptions, we refer readers to section II.E of this final rule with comment period.

h. Modifications to the Medicaid EHR Incentive Program

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the Medicaid EHR Incentive Program. In this final rule with comment period, we finalize the proposed changes to EHR reporting periods that would begin in 2017; Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time in the Medicaid EHR Incentive Program would be required to attest for an EHR reporting period of any continuous 90-day period in the calendar year for purposes of receiving an incentive, as well as avoiding the payment adjustment under the Medicare Program (80 FR 16779).

We will continue to allow states to set up a CQM submission process that Medicaid EPs and eligible hospitals may use to report on CQMs for 2017 and subsequent years. We are also finalizing amendments to state reporting on providers who are participating in the Medicaid EHR Incentive Program, as well as state reporting on implementation and oversight activities.

The provisions included in this final rule with comment period will apply for the Medicaid EHR Incentive Program, including the changes to the EHR reporting period in 2015 and 2016, and the objectives and measures required to demonstrate meaningful use in 2015 through 2017. We will continue to allow states flexibility under the Medicaid EHR Incentive Program for the public health reporting objective. Specifically, for meaningful use in 2015 through 2017 and for Stage 3, we will continue the policy stated in the Stage 2 final rule (77 FR 53979) to allow states to specify the means of transmission of the data or otherwise change the public health measure (as long as it does not require EHR functionality above and beyond that which is included in the certification requirements specified under the 2014 Edition certification criteria). We refer readers to section II.G of this final rule with comment period for further information on the Medicaid EHR Incentive Programs.

3. Summary of Costs and Benefits

Upon finalization, the provisions in this final rule with comment period are anticipated to have an annual effect on the economy of \$100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule with comment period.

Based on prior rulemaking, we expect spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2015 and 2017 to be \$14.2 billion; however, the policies in this final rule with comment period do not change estimates over the current period.

Our analysis of impacts for the policies in this final rule with comment period relate to the reduction in cost associated with provider reporting burden estimates for 2015 through 2017 as affected by the adopted changes to the current program. The estimates also relate to the transfer payments for incentives for Medicaid providers and reductions in payments for Medicare providers through payment adjustments for 2018 and subsequent years. For 2015 through 2017, we estimate the reduction in the reporting burden for providers demonstrating meaningful use in a calendar year as 1.45 to 1.9 hours per EP respondent and 2.62 hours per eligible hospital or CAH respondent. We estimate the total annual cost savings related to this reduction at \$52,547,132 for a low estimate and \$68,617,864 for a high estimate. We expect spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be \$3.7 billion (this estimate includes net payment adjustments in the amount of \$0.8 billion for Medicare providers who do not achieve meaningful use).

In this final rule with comment period, we do not estimate total costs and benefits to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance. Nonetheless, we believe there are substantial benefits that can be obtained by society (perhaps accruing to eligible hospitals and EPs), including cost reductions related to improvements in patient safety and patient outcomes and cost savings benefits through maximizing efficiencies in clinical and business processes facilitated by certified HIT.

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). Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the final rule with comment period.

B. Overview of the Regulatory History

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA) amended Titles XVIII and XIX of the Act to authorize incentive payments to EPs, eligible hospitals, CAHs, and MA organizations to promote the adoption and meaningful use of CEHRT. In the July 28, 2010 **Federal Register** (75 FR 44313 through 44588), we published a final rule (“Medicare and Medicaid Programs; Electronic Health Record Incentive Program”, or “Stage 1 final rule”) that specified the Stage 1 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, calculation of the incentive payment amounts, and other program participation requirements. For a full explanation of the amendments made by ARRA, see the Stage 1 final rule at 75 FR 44316. In the Stage 1 final rule, we also detailed that the Medicare and Medicaid EHR Incentive Programs would consist of three different stages of meaningful use requirements.

In the September 4, 2012 **Federal Register** (77 FR 53967 through 54162), we published a final rule (“Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; Final Rule,” or “Stage 2 final rule”) that specified the Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for incentive payments. In addition, the Stage 2 final rule finalized payment adjustments and other program participation requirements under Medicare for covered professional and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of CEHRT, finalized the revision of certain Stage 1 criteria, and finalized criteria that applied regardless of stage.

In the December 7, 2012 **Federal Register** (77 FR 72985), CMS and the Office of the National Coordinator for Health Information Technology (ONC) jointly published an interim final rule with comment period (IFC) titled “Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program” (December 7, 2012 IFC). The Department of Health and Human Services (HHS) issued the IFC to replace the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule published on September 4, 2012 in the **Federal Register** with updated versions of those standards.

The December 7, 2012 IFC also revised the Medicare and Medicaid EHR Incentive Programs by—

- Adding an alternative measure for the Stage 2 meaningful use objective for hospitals to provide structured electronic laboratory results to ambulatory providers;
- Correcting the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission; and
- Making the case number threshold exemption for CQM reporting applicable for eligible hospitals and CAHs beginning with FY 2013.

The December 7, 2012 IFC also provided notice of our intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012.

In the September 4, 2014 **Federal Register** (79 FR 52910 through 52933), CMS and ONC published a final rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule” (“2014 CEHRT Flexibility final rule”). Due to issues related to availability delays for EHR technology certified to the 2014 Edition, the 2014 CEHRT Flexibility final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 to continue to use one of the following options for reporting periods in CY 2014 and FY 2014, respectively—

- EHR technology certified to the 2011 Edition; or
- A combination of EHR technology certified to the 2011 Edition and EHR technology certified to the 2014 Edition for the EHR reporting periods.

Although the 2014 CEHRT flexibility final rule did not alter the attestation or hardship exception application deadlines for 2014, it did make changes to the attestation process to support these flexible options for CEHRT. This 2014 CEHRT Flexibility final rule also discussed the provisions of the December 7, 2012 IFC and finalized policies relating to the provisions contained in the December 7, 2012 IFC.

In the November 13, 2014 **Federal Register**, we published an interim final rule with comment period titled “Medicare Program; Revisions to

Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule” (79 FR 67976 through 67978) (November 13, 2014 IFC). Under this November 13, 2014 IFC, we recognized a hardship exception for EPs and eligible hospitals for 2014 under the established category of extreme and uncontrollable circumstances in accordance with the Secretary’s discretionary authority. To accommodate this hardship exception, we further extended the hardship application deadline for EPs and eligible hospitals to November 30 for 2014 only. We also amended the regulations to allow CMS to specify a later hardship application deadline for certain hardship categories for EPs, eligible hospitals, and CAHs.

In the March 30, 2015 **Federal Register**, we published a proposed rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3” (80 FR 16731 through 16804). In the Stage 3 proposed rule, we specified the proposed meaningful use criteria that EPs, eligible hospitals, and critical access hospitals must meet in order to demonstrate meaningful use of CEHRT for Stage 3 of the Medicare and Medicaid EHR Incentive Programs. The proposed rule also specified the proposed requirements for electronic submission of CQMs and created a single set of meaningful use requirements for Stage 3 that would be optional for providers in 2017 and required for all providers beginning in 2018. Finally, the Stage 3 proposed rule would also change the EHR reporting period so that all providers would report under a calendar year timeline.

In the April 15, 2015 **Federal Register**, we published a proposed rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017” (80 FR 20346 through 20399). In the proposed rule, we proposed to change the EHR reporting period in 2015 to a 90-day period aligned with the calendar year and to align the EHR reporting period in 2016 with the calendar year. In addition, in the proposed rule, we proposed to modify the patient action measures in the Stage 2 objectives related to patient engagement. Finally, we proposed to streamline the program by removing reporting requirements on measures that have become redundant, duplicative, or topped out through advancements in EHR function and provider performance for Stage 1 and

Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

For Stage 1 and Stage 2, CMS and ONC worked closely to ensure that the definition of meaningful use of CEHRT and the standards and certification criteria for CEHRT were coordinated. Current ONC regulations may be found at 45 CFR parts 170. CMS and ONC have worked together to align the Stage 3 proposed rule and the ONC 2015 Edition proposed rule (80 FR 16731 through 16804 and 80 FR 16804 through 16921), and again are working together to align the final rules.

Readers may also visit: <http://www.cms.hhs.gov/EHRincentiveprograms> and <http://www.healthit.gov> for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Introduction

When the Medicare and Medicaid EHR Incentive Programs began in 2011, the requirements for the objectives and measures of meaningful use were designed to begin a process of health care delivery system transformation aligning with foundational goals defined in the Health Information Technology for Economic and Clinical Health Act (HITECH) Act. The HITECH Act requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act); requiring the use of EHR technology, which defines both the functions that should be available within the EHR and the purpose to which those functions should be applied (see section 1848(o)(4) of the Act); and defining key foundational principles of meaningful use to support the improvement of care and care coordination, and the use of EHR technology to submit information on clinical quality measures and other measures (see section 1848(o)(2)(A) of the Act).

In 2015, we published two notices of proposed rulemaking in 2015 relating to the EHR Incentive programs to address near term goals in 2015 through 2017 and long-term goals for Stage 3 in 2017 and subsequent years.

In the March 30, 2015 Stage 3 proposed rule (80 FR 16734), we proposed the requirements for the Medicare and Medicaid EHR Incentive Programs for 2017 and subsequent years to build a long-term sustainable program

focused on the advanced use of CEHRT to support clinical effectiveness, health information exchange, and quality improvement. We proposed a total of eight objectives that focus on supporting advanced clinical processes, promoting interoperability and health information exchange, continuing progress in electronic public health reporting, and expanding the scope and methods for provider and patient engagement.

In the April 15, 2015 EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20347), we proposed modifications to Stage 1 and Stage 2 to reflect this long-term vision and to be responsive to the changing environment and stakeholder concern over program complexity and redundant reporting requirements. The proposed rule included a reduced set of objectives and measures based on the Stage 2 objectives and measures that align with the policies for Stage 3. The proposed rule also proposed removing measures that had become topped out, redundant or duplicative, and easing requirements around measures requiring providers to be accountable for patient action. We proposed the modifications to address stakeholder concerns and to continue to support the overall goal of the widespread adoption and meaningful use of CEHRT in efforts to transform our health care delivery system and improve health care quality.

Comment: Many commenters supported the policies proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule. A few commenters stated that the proposed rule was a more accurate reflection of what caregivers are able to provide to patients and the tools they have available to do so. Additionally, they stated that the proposals reflected what patients are willing to provide to the caregivers.

A few commenters indicated that CMS should update the measures and requirements to ensure they are appropriately aligned and would improve a provider's ability to successfully demonstrate meaningful use. A commenter stated that we should first receive provider input before adding or suggesting any changes to the requirements.

Response: We appreciate the supportive comments and reiterate that our goals include reducing the reporting burden, eliminating redundant and duplicative reporting, and better aligning the objectives and measures of meaningful use for 2015 through 2017 with the Stage 3 requirements.

We proposed revisions to the requirements according to provider and stakeholder feedback received through

correspondence, public forums, and listening sessions. Additionally, we proposed these changes through a notice of proposed rulemaking and accepted comments from the public during the comment periods for both proposed rules. We believe that providers helped to shape the requirements for meaningful use in part through those processes.

Comment: A few commenters stated that the proposal for the EHR Incentive Programs in 2015 through 2017 proposed rule imposes unreasonable financial constraints and reporting burdens. Other commenters stated the EHR Incentive Program in 2015 through 2017 proposed rule moves the program backward instead of forward. Another commenter stated that there are administrative burdens that providers face daily that distract from patient care or force implementation of alternative workflows or processes that do not relate to real-world care or improved quality and that the EHR Incentive Programs add to that burden.

Response: We understand cost and burden are factors for health care providers. As previously noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20386), the regulatory impact analysis outlines the reduction in the reporting burden for providers demonstrating meaningful use in 2015 and estimates the total annual cost savings. We believe the modifications to Stage 1 and Stage 2 in the EHR Incentive Programs in 2015 through 2017 proposed rule represent forward progress for the program by better aligning reporting periods for providers; supporting a flexible, clear framework to reduce provider burden; and ensuring future sustainability of the Medicare and Medicaid EHR Incentive Programs. We understand the competing demands on a provider's time. However, as we have stated previously in the Stage 3 proposed rule (80 FR 16735), we believe the efficiencies to be gained by the HIT user will provide a long-term benefit for providers and outweigh the short-term concern over revisions to workflows, staff training, and other administrative needs.

Comment: A commenter on the EHR Incentive Programs in 2015 through 2017 proposed rule stated that new measures should not be added and changes should either eliminate measures or reduce the measurement thresholds.

Response: We did not propose to add new measures to the EHR Incentive Programs in 2015 through 2017. We proposed to require that all providers attest to a reduced set of objectives and measures beginning in 2015. The

reduced set of objectives and measures are based on the existing Stage 1 and Stage 2 objectives and measures already required for the EHR Incentive Programs.

Additionally, we proposed to remove measures that we believe are redundant, duplicative, or topped out based on provider performance.

Comment: Many commenters on the Stage 3 proposed rule supported the proposals in the Stage 3 proposed rule to establish a single set of objectives and measures, align the Medicare and Medicaid EHR Incentive Programs timeline and requirements for clinical quality measure reporting with other CMS quality reporting programs that use CEHRT, and have optional Stage 3 participation in 2017.

Response: We appreciate the supportive comments and reiterate that our priority is to improve the efficiency, effectiveness, and flexibility of the EHR Incentive Programs by simplifying the reporting requirements and reducing the complexity of the program.

Comment: Several commenters on the Stage 3 proposed rule believed that the proposals made in the Stage 3 proposed rule would be burdensome, more time-consuming, and do little to improve patient care. Some commenters attributed the increased burden to increased measure thresholds.

Response: We recognize clinical workflows and maintaining documentation may require modifications upon implementation of the requirements for Stage 3. However, the changes were proposed in response to stakeholder concerns and designed to reduce burdens associated with the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods.

Patient-focused care is very important to us, and we have proposed to maintain measures specific to patient engagement and that support a patient's access to their health information. The measures promote increased communication between providers and their patients, while placing focus on a patient's involvement in their care.

As noted in the Stage 3 proposed rule, (80 FR 16734), Stage 3 is intended to align the timeline and requirements for clinical quality measure reporting in the Medicare and Medicaid EHR Incentive Programs with other CMS quality reporting programs that use CEHRT. This alignment is meant to reduce provider burden associated with reporting on multiple CMS programs and enhance CMS operational efficiency.

In addition, we understand that the increase in thresholds proposed in the Stage 3 rule may increase the work required to achieve an individual measure. However, we noted that part of our decision making process in the overall reduction of the number of objectives in the program was to reduce the burden on providers for those measures by allowing them to focus on advanced use objectives that support clinical effectiveness, patient safety, patient engagement, and care coordination. We believe providers should prioritize their efforts to strive to achieve high performance on these important measures. In addition, as noted in the proposed rule (80 FR 16740), the statute specifically requires the Secretary to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use (see, for example, section 1848(o)(2)(A)(iii) of the Act). Therefore, for these reasons, we intend to continue to use measure thresholds that may increase over time and to incorporate advanced use functions of CEHRT into meaningful use objectives and measures.

Comment: A commenter on the EHR Incentive Programs in 2015 through 2017 proposed rule suggested that with Stage 3 in place, the Physician Quality Reporting System (PQRS) program and the Hospital Inpatient Quality Reporting (IQR) Program should be eliminated in 2018.

Response: We cannot eliminate the PQRS and Hospital IQR Programs because they are required by statute (see sections 1848(a)(8) and 1886(b)(3)(B)(viii) of the Act, respectively). Furthermore, although PQRS payment adjustments sunset after 2018 in accordance with section 101(b)(2)(A) of MACRA, certain provisions and processes under PQRS will continue to apply for purposes of MIPS. MIPS is also required by statute (see section 1848(q) of the Act, as added by section 101(c) of MACRA). One of the focal points for Stage 3, however, is alignment with other quality programs such as the Hospital IQR Program and PQRS, not replacement of them.

Comment: A few commenters relayed concerns regarding financial issues related to costs associated with Stage 3 implementation, upgrading, installing, testing, and maintenance of EHRs that are outside of normal operating practices. A commenter stated maintenance of EHRs requires many expenses that surpass what is considered reasonable.

Response: We understand cost is a factor for health care providers. Our goal with Stage 3 is to simplify reporting

requirements, reduce program complexity, and focus on the advanced use of EHR technology to promote improved patient outcomes and health information exchange to minimize burdens placed on providers.

The Stage 3 objectives and measures were designed to focus on the three-part aim of better health, better care, and lower costs. We believe that the costs associated with EHR adoption and continued maintenance are outweighed by the long-term benefits a provider may experience from meaningfully using CEHRT, including practice efficiencies and improvements in medical outcomes. For example, EHR supported processes such as drug-drug and drug-allergy interaction and clinical decision support, as well as electronic prescribing and computerized provider order entry for medication orders, can all work in tandem to support a provider's efforts to effectively and safely prescribe and administer medications and reduce costs and risks associated with adverse events. In addition, while there may be a cost associated with HIT supported patient engagement as compared to not engaging with patients, the use of HIT allows providers to leverage economies of scale and engage with a large number and wide range of patients in ways not otherwise possible. Patient education and patient engagement in many forms support improved care and reduced cost of care as patients who are engaged with their health care have better outcomes and cost savings for their care.¹ The use of CEHRT, while representing a capital investment in procurement and maintenance, can result in improved care and long term cost reduction and we believe these investments provide a strong return on investment for both providers and patients in our healthcare system.

Comment: A commenter on the Stage 3 proposed rule recommended that CMS eliminate measures that focus on data entry in favor of measures that focus on interoperability. Some commenters stated the Medicare and Medicaid EHR Incentive Programs do little to establish or promote interoperability among providers, between providers and consumers, or among participants in the health information ecosystem. Some commenters stated that many of the

Stage 3 requirements depend on interoperability of EHR systems, which has not yet been realized except within health systems sharing the same software. These limited networks contribute to a decrease in patient access to care, choice, and timely availability of specialists, thus thwarting many of the overall objectives intended by the Medicare and Medicaid EHR Incentive Programs and creating a challenge for providers. Some commenters stated interoperability must expand in order for Stage 3 of the EHR Incentive Programs to generate the significant quality, safety, efficiency, coordination, and public health outcomes needed. Those commenters suggested that one approach to this challenge would be for CMS and ONC to establish an interoperability benchmark first, and then measure its progress.

Response: We disagree that the Medicare and Medicaid EHR Incentive Programs do little to establish or promote interoperability. As stated in the Stage 3 proposed rule (80 FR 16734), the Stage 3 measures and objectives are designed to promote interoperability with a focus on the advanced use of EHR technology, the use of electronic standards, and the interoperable exchange of health information between systems. The program leverages the ONC HIT Certification Program and the associated editions of certification criteria to ensure that eligible providers possess health IT that conforms with standards and the requirements for the capture and exchange of certain data in a structured format. This improves interoperability by ensuring that data within one system can be received and used by the recipient system. Various objectives within the Stage 3 proposed rule aim to increase interoperability through—

- Provider to provider exchange through the transmission of an electronic summary of care document;
- Provider to patient exchange through the provision of electronic access to view, download, or transmit health information; and
- Provider to public health agency exchange through the public health reporting objectives.

Research supports our belief that the policies established in the EHR Incentive Programs, the ONC HIT Certification Program, and the related effort to support provider participation at a state and national level have had a significant impact on the development of health information exchange infrastructure in the United States. For EHR reporting periods in 2014, more than 3,700 eligible hospitals and CAHs

¹ Recent research cites an 8 percent cost of care reduction in the first year and 20 percent in subsequent years attributable to patient engagement.

Hibbard, Judith H and Jessica Greene. "What The Evidence Shows About Patient Activation: Better Health Outcomes And Care Experiences; Fewer Data On Costs" *Health Affairs*: February 2013 32:207–214.

and more than 232,000 EPs received incentive payments under the EHR Incentive Programs for meaningful use of CEHRT, which included exchanging health information electronically with other providers and with their patients. In addition, research shows a significant shift since the program began in 2011. Hospital electronic health information exchange (HIE) with other hospitals or ambulatory care providers outside their organization increased by 85 percent from 2008 to 2014 and increased by 23 percent since 2013.²

The Stage 3 proposed rule focuses less on data capture and entry and more on interoperable health data sharing by including additional functions and requirements for the transmission and consumption of standardized health data through electronic exchange. The proposed Stage 3 objectives can essentially be broken into 2 categories:

- Category 1 objectives that support clinical effectiveness and patient safety, and
- Category 2 objectives that support health information exchange.

For Category 2, four of the eight proposed objectives are clearly focused on the electronic exchange of health information through interoperable systems: Patient Electronic Access, Coordination of Care through Patient Engagement, Health Information Exchange, and Public Health and Clinical Data Registry Reporting. Each of these objectives involves the capture of structured data using a standard and the transmission of that data in a standardized format that can be sent, received, and incorporated electronically. These objectives build on the transmission standards established in prior rules by incorporating receipt standards and consumption requirements for HIE. We also proposed to expand the technology functions that may be used for transmission including a wider range of options, such as application-program interface (API) functionality.

In addition, two of the three objectives that fall into the first category (for example, computerized provider order entry and electronic prescribing) may also be categorized as objectives that support the interoperable exchange of health information through the process of creating and transmitting prescriptions, medication orders, laboratory order, and diagnostic imaging orders using standards established by CEHRT for that purpose.

We believe this continued emphasis on requiring standards in the technology

and the use of these standards in clinical settings will continue to support and promote interoperability. Furthermore, we believe the expansion of the requirements around data transmission will continue to drive use and the ongoing development and strengthening of an interoperable HIE infrastructure.

We also received numerous comments on the EHR Incentive Programs in 2015 through 2017 and Stage 3 proposed rules during the public comment periods that were either unrelated to the Medicare and Medicaid EHR Incentive Programs or outside the scope of the proposed rules. These comments included considerations for future rulemaking activities, requests for new incentives for various provider types that are not currently eligible to participate, requests to create a sliding scale for payment adjustments, and support or recommendations for ONC's 2015 Edition proposals. We thank all the commenters for their suggestions and feedback on the Medicare and Medicaid EHR Incentive Programs. However, comments unrelated to the proposals fall outside the scope of the proposed rule and are not addressed in this final rule with comment period.

B. Meaningful Use Requirements, Objectives, and Measures

1. Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs

a. Uniform Definitions

We proposed changes to the uniform definitions in part 495 subpart A of the regulations, in both the Stage 3 proposed rule (80 FR 16736 through 16737) and the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20351 through 20352). We proposed to maintain these definitions, unless specifically stated otherwise in the proposed rule. We proposed moving to a single set of criteria for meaningful use, which we herein call Stage 3, in order to eliminate the varying stages of the Medicare and Medicaid EHR Incentive Programs. We proposed that a modified version of Stage 1 and Stage 2 would be applicable for 2015 through 2017. We proposed that the Stage 3 definition of meaningful use would be optional for providers in 2017 and mandatory for all providers beginning in 2018. To support these changes, we proposed revising the uniform definitions under 42 CFR 495.4 for "EHR reporting period" and "EHR reporting period for a payment adjustment year," as discussed in sections II.B.1.b.(3) and section II.E.2.2 of this final rule with comment period.

b. Definitions for 2015 Through 2017, and 2017 and Subsequent Years

In the Stage 3 proposed rule (80 FR 16737), we sought to streamline the criteria for meaningful use. We intended to do this by—

- Creating a single stage of meaningful use objectives and measures (herein called Stage 3) that would be optional for all providers in 2017 and mandatory for all providers in 2018;
- Allowing providers flexible options for 2017;
- Changing the EHR reporting period to a full calendar year for all providers; and
- Aligning with other CMS quality reporting programs using CEHRT, such as PQRS and Hospital IQR, for clinical quality measurement.

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed changes to a number of definitions previously finalized for the EHR Incentive Programs in the Stage 1 and Stage 2 final rules in order to modify the program in response to the changing HIT environment and related stakeholder concerns. These changes address the following:

- An overall simplification of the program aligned to the overarching goals of sustainability, as discussed in the Stage 3 proposed rule (80 FR 16737) and in section II.B.1.b.(1) and (4) of this final rule with comment period, and a related change to requirements necessary to accommodate these changes, outlined in sections II.B.1.b.(2), and (3), of this final rule with comment period.
 - Moving all providers to an EHR reporting period aligned with the calendar year, as outlined in section II.B.1.b.(3).A. of this final rule with comment period.
 - Allowing flexibility for providers in 2015 to accommodate the proposed changes, as outlined in section II.B.1.b. of this final rule with comment period.
 - Removing requirements for objectives and measures that are redundant or duplicative or that have "topped out," as described in the Stage 3 proposed rule (80 FR 16741 through 16742) and outlined in section II.B.1.b.(4).(a), of this final rule with comment period.
 - Restructuring the remaining measures and objectives to streamline requirements for 2015 through 2017 and to accommodate the changes for an EHR reporting period in 2015, as outlined in section II.B.1.b.(2), and (3), and II.B.1.b.(4).(b), of this final rule with comment period.
 - Refocusing the existing program so that it is building toward advanced use

² http://www.healthit.gov/sites/default/files/data-brief/ONC_DataBrief24_HIE_Final.pdf.

of EHR technology, aligned with the Stage 3 proposed rule (80 FR 16741) through maintaining the objectives and measures outlined in section II.B.2 of this final rule with comment period.

(1) Stages of Meaningful Use

In the phased approach to meaningful use, we finalized the criteria for meaningful use through incremental rulemaking that covered Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs. (For further explanation of the criteria we finalized in Stage 1 and Stage 2, we refer readers to 75 FR 44314 through 44588, 77 FR 53968 through 54162, and 79 FR 52910 through 52933.)

In the Stage 3 proposed rule (80 FR 16737 through 16739), we proposed to set a new foundation for this evolving program by proposing a number of changes to the Medicare and Medicaid EHR Incentive Programs. First, we proposed a definition of meaningful use that would apply beginning in 2017. This definition, although herein referred to as Stage 3, would be the only definition for the Medicare and Medicaid EHR Incentive Programs and would incorporate certain requirements and aspects of Stage 1 and Stage 2. Beginning with 2018, we proposed to require all EPs, eligible hospitals, and CAHs, regardless of their prior participation in the Medicare and Medicaid EHR Incentive Programs, to satisfy the requirements, objectives, and measures of Stage 3. However, for 2017, we proposed that Stage 3 would be optional for providers. This proposed option would allow a provider to meet to Stage 3 in 2017 or to remain at Stage 2 or Stage 1, depending on their prior participation.

Furthermore, we proposed that Stage 3 would adopt a simplified reporting structure on a focused set of objectives and associated measures to replace all criteria under Stage 1 and Stage 2. Specifically, we proposed criteria for meaningful use for EPs, eligible hospitals, and CAHs (optional in 2017 and mandatory beginning in 2018), regardless of a provider's prior participation in the Medicare and Medicaid EHR Incentive Programs.

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed to further reduce complexity in the program and to realign the current program to work toward this overall shift to a single set of objectives and measures in Stage 3 in 2018. We proposed to require that all providers attest to a single set of objectives and measures beginning with an EHR reporting period in 2015 instead of waiting until Stage 3 in 2018. Because

this change may occur after providers have already begun their work toward meeting meaningful use in 2015, we proposed accommodations within individual objectives for providers in different stages of participation. These accommodations include retaining the different specifications between Stage 1 and Stage 2 and allowing special exclusions for certain objectives or measures for EPs previously scheduled to participate in Stage 1 for an EHR reporting period in 2015.

We proposed all providers would be required to attest to certain objectives and measures finalized in the Stage 2 final rule that would align with those objectives and measures proposed for Stage 3 of meaningful use. In effect, this would create a new progression using the existing objectives and measures where providers attest to a modified version of Stage 2 with accommodations for Stage 1 providers (equivalent to a reduced version of Stage 3) in 2015; a modified version of Stage 2 in 2016 (equivalent to a reduced version of Stage 3); either a modified version of Stage 2 (equivalent to a reduced version of Stage 3) or the full version of Stage 3 outlined in the Stage 3 proposed rule in 2017; and the full version of Stage 3 outlined in the Stage 3 proposed rule beginning in 2018 (80 FR 16738).

We sought comment on whether or not we should implement only the modifications proposed in the rule from 2015 through 2017 (80 FR 20351 through 20353) and begin Stage 3 in 2018 without an option year in 2017, or if we should allow providers the option to demonstrate Stage 3 beginning in 2017 as discussed in the Stage 3 proposed rule (80 FR 16738).

Comment: Several commenters supported the option of moving to Stage 3 or remaining in Modified Stage 2 in 2017 in the EHR Incentive Program in 2015 through 2017 proposed rule. Many commenters believed that having the option to attest to Stage 3 in 2017 would allow vendor development and upgrades to be spread over a longer period of time. Other providers supported the option for providers to attest to either Stage 1, Stage 2, or Stage 3 in calendar year 2017.

Numerous commenters on the EHR Incentive Program in 2015 through 2017 proposed rule supported the proposal to move all providers to Stage 3 in 2018. They stated it is very complicated to keep track of all providers and their various programs, stages, and years, and that the proposed approach would ease the burden associated with reporting different stages of meaningful use. Numerous commenters on the Stage 3

proposed rule supported the proposal to move all providers to Stage 3 in 2018.

Response: We appreciate the number of commenters who supported the proposal for optional Stage 3 participation in 2017. We believe the option to attest to Stage 3 in 2017 offers flexibility for those providers ready to move forward to Stage 3 requirements, while allowing additional time for providers who may need to update, implement, and optimize the technology certified to the 2015 Edition. We believe vendors, developers, and providers will have an appropriate amount of time between the publication date of the final rule with comment period and 2018 to transition to Stage 3.

We thank commenters for their support of the proposal to move all providers to Stage 3 in 2018. As noted in the EHR Incentive Programs in 2015 through 2017 proposed rule, the proposal was based in part on comments received in earlier rulemaking that relayed confusion and concerns regarding increased reporting burden related to the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods.

Comment: We received multiple comments on the Stage 3 proposed rule opposing the proposal to move all providers to Stage 3 in 2018. Commenters indicated this proposal changes CMS' prior plan to permit providers who had not spent 2 years in either Stage 1 or Stage 2 to remain in that stage for a second year before transitioning to Stage 3. A commenter suggested that CMS consider extending Stage 1 and Stage 2 requirements for 2015 through 2017 to also include 2018. A few commenters stated providers should remain in each stage of meaningful use for 3 years to allow sufficient time to update, implement, and optimize the new technology. Some commenters requested that CMS delay Stage 3 to 2019 or later based on a lack of data related to experience for Stage 2.

Response: We appreciate the feedback from commenters. We recognize that our proposals would modify our earlier approach of allowing providers to remain in Stage 1 and Stage 2 for 2 years prior to transitioning to Stage 3. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed to reduce the complexity of the program by proposing to require providers to attest to a single set of objectives and measures starting in 2015. We proposed alternate exclusions and specifications for 2015 to accommodate Stage 1 providers working toward demonstration of meaningful use in 2015. Therefore, the combination of

Stage 1 and Stage 2 objectives and measures into a single stage (Modified Stage 2) beginning in 2015 effectively removes the “Stage” designation. Under our proposal, providers would have the option to meet the single set of objectives and measures for Modified Stage 2 for up to 3 years (2015 through 2017) prior to moving to Stage 3. We are therefore removing the requirement that providers remain in each Stage for a set number of years because we believe our proposal to streamline the objectives and measures reduces the complexity of the program.

We proposed to align the objectives and measures of meaningful use for 2015 through 2017 with the Stage 3 objectives and measures in part because we believe this will provide a smoother transition for providers to Stage 3. Additionally, we believe that interoperability and EHR functionalities will continue to advance prior to 2018, when Stage 3 would be required of all eligible providers, which should increase providers’ success in meeting the program requirements. Multiple providers have expressed their support for the option to attest to Stage 3 in 2017, indicating confidence in the transition. Therefore, we are maintaining the timeframe for implementation of Stage 3.

Comment: Some commenters believed that Stage 3, like its predecessors, takes a “one size fits all” approach with requirements that may not be applicable to all eligible participants.

Response: We disagree that Stage 3 is a “one size fits all” approach. We believe our proposal for Stage 3 allows flexibility within the objectives to allow providers to focus on implementations that support their practice. For example, we proposed to incorporate flexibility for the Stage 3 objectives of Coordination of Care through Patient Engagement, Health Information Exchange, and Public Health Reporting so that providers can choose the measures most relevant to their unique practice setting.

Comment: A few commenters on the EHR Incentive Program in 2015 through 2017 proposed rule expressed concern that providers entering the program in 2015 or 2016 and those experiencing financial constraints would have difficulty moving to Stage 3 in 2018.

Response: As previously noted, we proposed to align the objectives and measures of meaningful use for 2015 through 2017 with the Stage 3 objectives and measures. We believe that the modified Stage 2 we proposed for 2015 through 2017 will provide a smoother transition for providers to Stage 3, including new participants in the

program. For example, new participants who would otherwise have been in Stage 1 will be able to take advantage of the alternate exclusions and specifications of these Modified Stage 2 requirements. We understand cost is a factor for health care providers. However, as noted in prior rules, we believe the benefits of EHR adoption outweigh the potential costs (for more information, see the Stage 2 final rule at 77 FR 53971).

Comment: A commenter on the Stage 3 proposed rule requested clarity on the expectations for the 90-day “gap” hospitals will have from October 1 through December 31, 2016, and whether hospitals need to demonstrate meaningful use during that timeframe.

Response: In the Stage 3 proposed rule (80 FR 16739 through 16740), we noted a possible reporting gap from October 1 through December 31, 2016 as a result of our proposal to align the EHR reporting period for eligible hospitals and CAHs with the calendar year beginning in 2017. After the Stage 3 proposed rule was published, we published the EHR Incentive Program in 2015 through 2017 proposed rule, in which we proposed this alignment with the calendar year would begin earlier, in 2015, eliminating the potential for a gap in the fourth quarter of CY 2016.

Comment: Some commenters on the EHR Incentive Program in 2015 through 2017 proposed rule opposed having an option to attest to Stage 3 in 2017, stating that keeping providers at the same stage allows performance to remain at the same level, thereby making it easier to track and measure. Additional commenters stated the option does not support CMS efforts to streamline the EHR Incentive Programs.

A few commenters were concerned that many providers will have difficulty attesting to Stage 3 in 2017 if other collaborating partners are not operating with the same CEHRT.

A few commenters indicated that a provider electing to attest to a later stage was a rarity in previous years when given an option.

Response: We thank commenters for their feedback. First, we note that providers have not been given an option to move forward in their Stage progression in the past, and that CMS has in fact received multiple requests to allow providers to do so in past years. Second, we understand the challenges faced by providers who are not ready or able to move to Stage 3 in 2017. However, as other comments have shown, several stakeholders are supportive of the option for 2017 and, because it is an option and not a requirement for 2017, providers would

not be required to meet Stage 3 requirements in 2017 if they were not ready to do so. Finally, the meaningful use objectives and measures proposed for 2015 through 2017 align with the objectives and measures proposed for Stage 3. Therefore, we believe many providers may seek to work toward meeting Stage 3 in 2017. If they find they are unable to meet the Stage 3 requirements, they would be able to successfully attest to Modified Stage 2 in 2017. Additionally, there is no requirement nor any technological limitation on providers to only collaborate with other providers with EHR technology certified to the same Edition of certification criteria. In fact, many of the certification criteria are similar between the 2014 Edition and the 2015 Edition. Therefore, we believe the transition to Stage 3 will be less complex and the program will be more streamlined moving forward. We believe offering the option of a transitional year in 2017 would enable providers to weigh the risks and benefits of moving to Stage 3 and decide for themselves what is most appropriate based on their individual circumstances.

Comment: Regarding the EHR Incentive Program in 2015 through 2017 proposed rule, other commenters stated that the timeline in the proposed rule represents an aggressive deadline for health IT vendors and developers supporting customers who might choose to begin Stage 3 in 2017. A few commenters stated removal of the option to participate in Stage 3 in 2017 would give EHR vendors and developers an additional 12 months to deploy EHR Technology certified to the 2015 Edition.

Response: We recognize stakeholder concerns and the potential burden that these changes may have on vendor upgrades in relation to timing for system changes. We believe that some vendors, developers, and providers will be able to make the necessary system changes in time to implement Stage 3 in 2017. We encourage discussion between vendors, developers, and providers on the feasibility to upgrade to EHR technology certified to the 2015 Edition and attest to Stage 3 in 2017. However, we remind commenters that this upgrade is optional in 2017 and for those providers who choose to attest to Modified Stage 2 and not to Stage 3, EHR technology certified to the 2015 Edition would not be required until 2018. In addition, providers may also choose to upgrade some modules as early as 2016 if the CEHRT is available.

Comment: The majority of commenters on the Stage 3 proposed rule supported the option of

participating in Stage 3 in 2017 and of using technology certified to either the 2014 or 2015 Edition in 2017 and believed this would provide relief to the industry. Some commented they would support this flexibility in all future years where changes to CEHRT will be required and noted transitioning to technology certified to a new Edition can be complex and can require more resources and time than anticipated. Other commenters suggested that providing an optional year to transition to technology certified to a new Edition allows the time necessary to help ensure a safe transition for patients and a smoother transition for providers. Other commenters were also appreciative of CMS' response to their concerns as reflected in the Stage 3 proposed rule.

Some commenters on the EHR Incentive Program in 2015 through 2017 proposed rule indicated that in the case of unanticipated challenges or delays with the adoption and implementation of the technology certified to the 2015 Edition, CMS should preemptively detail alternative scenarios to avoid future rule changes.

However, other commenters stated that 2017 is not a realistic start date for Stage 3 due to the expected timing of the final rule; necessary upgrades to technology; transitional processes after deployment such as training, workflow, and validation of reporting; and full year reporting requirements. A commenter suggested there would be only 12–15 months from the publication date of the final rule (assuming publication in late 2015) until technology certified to the 2015 Edition would need to be available from vendors and developers and implemented by organizations with necessary staff training completed for new workflows. Some commenters indicated EHR vendors and developers need on average 18 months to develop, test, market, and implement new functionality, while providers need lead time to re-work their processes and systems to new or revised requirements. Other commenters indicated concern about the timeline of transitioning to Stage 3 in 2017 and 2018, stating that 18 months is the minimum length of time needed between the final rules and the start of any stage of the EHR Incentive Program. Furthermore, as the change requires a technology upgrade, and given the likely timing for the publication of the final rules, the

proposed Stage 3 timetable will not allow for a full 18-month timeline before the beginning of Stage 3 as an option in 2017.

Some commenters on the EHR Incentive Program in 2015 through 2017 proposed rule indicated that in case of unanticipated challenges or delays with the adoption and implementation of the technology certified to the 2015 Edition, CMS should proactively detail alternative scenarios to avoid future rule changes.

Response: We appreciate the commenters' feedback and seek to explain a few points related to the proposed option for providers to participate in Stage 3 in 2017. First we note that providers may upgrade to EHR technology certified to the 2015 Edition when it becomes available. We note that CMS will allow a provider to successfully attest in 2015, 2016, or 2017 with technology certified to either the 2014 Edition, the 2015 Edition, or a combination of the two as long as, as the technology possessed can support the objectives and measures to which they plan to attest. Therefore, providers may adopt technology certified to the 2015 Edition prior to 2017, either in a modular approach or in total, and may still choose to attest to Modified Stage 2 and wait to begin Stage 3 until 2018.

Providers who are seeking to demonstrate Stage 3 in 2017 cannot do so without the support of certain functions that are only available for certification as part of the 2015 Edition certification criteria. This means that for 2017 a provider must have at least a combination of EHR technology certified to the 2014 Edition and the 2015 Edition in order to support participation in Stage 3. However, as Stage 3 is optional, providers are not required to upgrade to technology certified to the 2015 Edition until 2018.

As discussed further in section II.B.3 of this final rule with comment period, this means providers have flexibility to use EHR technology certified to either the 2014 or 2015 Edition (or a combination of CEHRT modules certified to different Editions). We proposed the flexibility to allow providers to move forward with upgrading their EHR technology at their own speed and to optionally attest to Stage 3 in 2017 if they are able to do so.

In total, these proposals allow for a staggered upgrade timeline for developers and providers of more than

24 months between the date of the publication of this final rule with comment period and 2018, when providers must begin using EHR technology certified to the 2015 Edition.

Because of this more than 24 month lead time for development, we do not anticipate significant challenges or delays in the adoption and implementation of the 2015 Edition CEHRT. We will continue to monitor and assess providers' progress towards adoption and implementation as EHR technology certified to the 2015 Edition becomes available.

Comment: Some commenters on the Stage 3 proposed rule noted the previous transitional difficulties for Stage 2 and recommended removing the option to demonstrate Stage 3 in 2017 and only require the Modified Stage 2 in 2017. These commenters suggested keeping the required start of Stage 3 at 2018, but allowing a 90-day or calendar year quarter EHR reporting period for the first year of Stage 3 in 2018.

Response: We disagree with the recommendation to remove the option of demonstrating Stage 3 in 2017. Although recognizing that not all providers will have the necessary technology to move to Stage 3 in 2017, many commenters supported allowing this option for those providers who are able to do so and we wish to maintain this proposed flexibility for providers. We address the suggestion for a 90-day EHR reporting period for Stage 3 in further detail in section II.B.1.b.(3).(iii) of this final rule with comment period.

After consideration of the public comments received, we are finalizing our approach to the timing of the stages of meaningful use as proposed in the EHR Incentive Program in 2015 through 2017 proposed rule and the Stage 3 proposed rule. We are finalizing that all EPs, eligible hospitals, and CAHs must attest to the Modified version of Stage 2 beginning with an EHR reporting period in 2015, with alternate exclusions and specifications for certain providers, as discussed further in section II.B.1.b.(4).(b).(iii) of this final rule with comment period. We finalize as proposed the option for all EPs, eligible hospitals, and CAHs to attest to Stage 3 for an EHR reporting period in 2017 and the requirement for all providers to attest to Stage 3 beginning with an EHR reporting period in 2018.

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY FIRST YEAR

First year demonstrating meaningful use	Stage of meaningful use				
	2015	2016	2017	2018	2019 and future years
2011	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2012	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2013	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2014	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2015	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2016	NA	Modified Stage 2	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2017	NA	NA	Modified Stage 2 or Stage 3.	Stage 3	Stage 3.
2018	NA	NA	NA	Stage 3	Stage 3.
2019 and future years	NA	NA	NA	NA	Stage 3.

We are adopting these provisions under the definition of a “Meaningful EHR user” at § 495.4 as noted in section II.B.1.b.(2) of this final rule with comment period and as noted in further detail in section II.B.2.a. and II.B.2.bof this final rule with comment period.

(2) Meaningful EHR User

In the Stage 3 proposed rule (80 FR 16737), we proposed to modify the definition of “Meaningful EHR user” under 42 CFR 495.4 to include the Stage 3 objectives and measures defined at § 495.7.

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR

20353), we additionally proposed to redesignate some of the numbering of the regulation text under part 495 to more clearly identify which sections of the regulation apply to specific years of the program. The redesignated numerical references for the regulation text are as follows:

Current section designation	Proposed section redesignation
§ 495.6—Objectives and Measures	§ 495.20—Objectives and Measures Prior to 2015.
§ 495.7*—Stage 3 Objectives and Measures	§ 495.22—Objectives and Measures Beginning in 2015.
§ 495.8—Demonstration of Meaningful Use	§ 495.24—Stage 3 Objectives and Measures.
§ 495.10—Participation Requirements	§ 495.40—Demonstration of Meaningful Use.
	§ 495.60—Participation Requirements.

* Indicates a new section that was proposed in the Stage 3 proposed rule. We indicated that all proposed changes in part 495 would be reconciled through this final rule with comment period.

We received no comments specific to these proposals, and therefore, are finalizing them without modification.

(3) EHR Reporting Period

In both the EHR Incentive Program in 2015 through 2017 and Stage 3 proposed rules (80 FR 16739 and 80 FR 20353), we proposed changes to the EHR reporting period in order to accomplish the following:

- Simplify reporting for providers, especially groups and diverse systems.
- Support further alignment with CMS quality reporting programs using certified health IT such as Hospital IQR and PQRS.
- Simplify HHS system requirements for data capture.
- Provide for greater flexibility in developing, implementing, stress testing, and conducting Quality Assurance (QA) of systems before deployment.

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20353), we proposed changes to the uniform definition of an “EHR reporting period” in § 495.4 beginning in 2015. We proposed similar changes to the definition of an “EHR reporting period for a payment adjustment year” in § 495.4 beginning in 2015, as discussed in section II.E.2of this final rule with comment period. We proposed changes to the attestation deadlines for purposes of the incentive payments and payment adjustments as discussed in section II.D of this final rule with comment period.

(i) Calendar Year Reporting

In the EHR Incentive Program 2015 through 2017 proposed rule (80 FR 20354), beginning in 2015, we proposed to change the definition of “EHR reporting period” at § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would begin and end in relation to a calendar year.

We proposed all providers (EPs, eligible hospitals, and CAHs) would be required to complete an EHR reporting period within January 1 and December 31 of the calendar year in order to fulfill the requirements of the EHR Incentive Programs. We proposed that for 2015 only, eligible hospitals and CAHs may begin an EHR reporting period as early as October 1, 2014 and must end by December 31, 2015. Beginning with 2016, the EHR reporting period must be completed within January 1 and December 31 of a calendar year.

For the payment adjustments under Medicare, we proposed changes to the EHR reporting periods applicable for payment adjustment years in the EHR Incentive Program 2015 through 2017 proposed rule at 80 FR 20379.

Comment: The majority of commenters for the EHR Incentive Program in 2015 through 2017 proposed rule supported the move to calendar year reporting for all providers and

believed this would simplify the reporting, monitoring, and attestation for hospitals. Other commenters stated aligning the reporting period would ease provider reporting burden for larger organizations that will not have to track their providers through different stages. Another commenter stated that this not only allows those health IT vendors and developers who service both outpatient and inpatient clients to be better aligned in their deployment and support, but also permits them to better harmonize technology implementation and program reporting. Other commenters stated that calendar year reporting, combined with the new "Active Engagement" options for public health and clinical data registry reporting (see section II.B.2.a.x of this final rule with comment period), will permit them to onboard, test, and deploy participants in a timely manner based upon the ability to meet their own internal resource constraints, while ensuring all participants can meet their meaningful use objectives.

Response: We thank the commenters for support of this proposal. As we stated in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20353), the movement of all providers to calendar year reporting supports program alignment and simplifies reporting requirements among provider types.

Comment: A commenter stated the move to reporting on the calendar year would eliminate the 3-month gap that currently exists between the end of the hospital EHR reporting period and the end of the EPEHR reporting period. This could cause issues, especially among organizations that share resources to support build, testing, and report validation for eligible hospitals, CAHs, and EPs. Other commenters stated aligning all providers to a calendar year would diminish their time to troubleshoot unexpected issues with final reports and validate the accuracy of data or lead to an increased risk in data entry errors in order to meet the February deadline for attestation for both EPs, eligible hospitals, and CAHs.

Response: We understand the concerns stated by stakeholders over the changes proposed for the EHR reporting periods. Because this final rule with comment period maintains the existing definitions for the objectives and measures, including the numerator and denominator calculations and measure thresholds for 2015, we believe vendors, developers, and providers will have minimal issues in the upgrades and testing for 2015. Likewise, the requirements for 2015 through 2017 use the existing measure specifications and

EHR technology requirements with minimal changes. Finally, the hospital attestation period is currently October 1 through the end of November of a given year, while the new attestation period was proposed as January 1 through the end of February. The attestation window would still be the same amount of time, and with the single period providers (especially those organizations that support both EPs and hospitals) can plan for testing and data validation for all settings in advance of the required deadline for attestation.

Comment: A few commenters on the EHR Incentive Program in 2015 through 2017 proposed rule stated that hospitals should be able to choose whether to report on a fiscal or calendar year basis in 2015 and 2016. Some commenters indicated that the proposed change to calendar year reporting would delay incentive payments for at least 3 months and cause financial and budgeting challenges. Additionally, some of the commenters stated hospitals have already made reporting plans and fiscal projections for these years.

Response: We disagree with the commenters' recommendation to allow hospitals to choose a fiscal or calendar year EHR reporting period in 2015 and 2016. Allowing hospitals this option would be inconsistent with the goal of program simplification and alignment. We agree that for most eligible hospitals and CAHs, this change would shift the incentive payment by one quarter within the same federal fiscal year. However, these are incentive payments and not reimbursements and, as noted in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20376), we believe the potential negative impact of this change would be minimal and outweighed by the opportunity to capitalize on efficiencies created by aligning the EHR reporting periods across EPs, eligible hospitals, and CAHs.

Comment: A commenter stated this alignment would further stress the CMS reporting system because the systems currently struggle to handle the surge of activity that occurs with the staggered reporting periods. The commenter suggested we improve the capacity of the attestation systems to ease the burden of the reporting process.

Response: We understand the commenter's concerns. However, historical evidence has shown that the vast majority of the more than 200,000 EPs have attested during the open attestation window from the beginning of January through the end of February and have done so successfully each year. In addition, consistent with past experience, the expectation and

planning for the CMS systems in 2015 was that the majority of providers would be attesting during this time, as most would have been required to attest for a full year EHR reporting period. The addition of fewer than 5,000 attestations by eligible hospitals and CAHs during this time will not significantly impact the load on the system. We do recommend that providers try to attest in January and not wait until the end of February to allow adequate time to address any issues that may arise, such as issues related to the accuracy of their attestation or their contact and banking information. CMS will also monitor readiness and attestation progress throughout the period and work to mitigate any risk that should arise.

After consideration of the public comments received, we are finalizing the proposal in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348) to align the EHR reporting period for eligible hospitals and CAHs with the calendar year beginning in 2015. For 2015 only, eligible hospitals and CAHs may begin an EHR reporting period as early as October 1, 2014 and must end by December 31, 2015. Beginning with 2016, the EHR reporting period must be completed within January 1 and December 31 of the calendar year. We made corresponding revisions to the definition of an "EHR Reporting Period" at § 495.4. For the payment adjustments under Medicare, we discuss the duration and timing of the EHR reporting period in relation to the payment adjustment year in section II.E.2 of this final rule with comment period.

(ii) EHR Reporting Period in 2015 Through 2017

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20354), we proposed to allow a 90-day EHR reporting period in 2015 for all providers to accommodate implementation of the other changes proposed in that rule. For 2015 only, we proposed to change the definition of "EHR reporting period" at § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period in 2015 would be any continuous 90-day period within the calendar year. We proposed that for an EHR reporting period in 2015, EPs may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015.

We proposed that in 2016, for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year, the EHR reporting period would be any continuous 90-day period between January 1, 2016 and December 31, 2016. However, for all returning participants that have successfully demonstrated meaningful use in a prior year, the EHR reporting period would be a full calendar year from January 1, 2016 through December 31, 2016.

For the payment adjustments under Medicare, we proposed changes to the EHR reporting periods applicable for payment adjustment years in the EHR Incentive Programs in 2015 through 2017 proposed rule at (80 FR 20379).

Comment: All comments received on the EHR Incentive Program in 2015 through 2017 proposed rule overwhelmingly supported the 90-day EHR reporting period in 2015. Many commenters stated the 90-day EHR reporting period would be beneficial for small and rural providers and provide the time needed to implement the required changes for the next stage of meaningful use. Other commenters stated that this is essential due to vendors and developers struggling to keep their systems up-to-date with all the changes and new requirements.

We also received numerous comments on the Stage 3 proposed rule strongly supporting the proposal for a 90-day EHR reporting period for all providers in 2015. Some commenters noted that the reduction to a 90-day EHR reporting period would assist providers transitioning from Stage 1 to Stage 2 without compromising patient care. Another commenter stated changing to any continuous 90 days (as opposed to calendar quarters) allows for needed flexibility in the event of unforeseen circumstances that could otherwise impede reporting within the originally planned timeframe.

Response: As stated in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20348), this 90-day EHR reporting period in 2015 would allow providers additional time to address any remaining issues with the implementation of EHR technology certified to the 2014 Edition and to accommodate the proposed changes to the objectives and measures of meaningful use for 2015. We also proposed an EHR reporting period of any continuous 90 days not tied to a specific calendar quarter in 2015.

Comment: A commenter on the EHR Incentive Program in 2015 through 2017 proposed rule suggested that the 90-day EHR reporting period was too short. Another commenter stated that he or

she believes the modification to the EHR reporting period would present a real and material risk to patients and that patients should have the benefit of a full year EHR reporting period. However, some commenters stated that if a provider can demonstrate meaningful use for 90 days, that provider must have the technology and workflows in place for meaningful use and therefore should not be required to submit a full year of data to confirm they are in compliance.

Response: We agree that a full year EHR reporting period is the most effective way to ensure that all actions related to patient safety that leverage CEHRT are fully enabled for the duration of the year. This is one of the primary considerations of our continued push for full year reporting whenever feasible, in addition to promoting greater alignment with other CMS quality reporting programs. However, we stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348) that a 90-day EHR reporting period would allow providers additional time to address any remaining issues related to implementation of technology certified to the 2014 Edition. A 90-day EHR reporting period is necessary in order to accommodate the proposed changes to the program that reduce the overall burden on providers to allow greater focus on the objectives and measures that promote patient safety, support clinical effectiveness, and drive toward advanced use of health IT. Despite the allowance for a 90-day EHR reporting period, we believe it is essential to maintain the processes and the workflows supporting and promoting patient safety enabled and fully implemented throughout the year. The EHR reporting period alone should not dictate a provider's commitment to patient safety.

In response to commenters who suggest that, in the future, demonstrating meaningful use for a 90-day period should serve as confirmation of a full year of compliance with program requirements, we note that if a provider does have the necessary workflows and processes in place for a full year there is no valid reason that provider should not demonstrate meaningful use for a full year. If extreme circumstances outside of the provider's control prohibit a full year of meaningful use, the provider may file for a hardship exception from the Medicare payment adjustments.

Comment: A commenter in the EHR Incentive Programs in 2015 through 2017 proposed rule requested quarterly reporting, stating that it is far more efficient and that eligible hospitals and

EPs are now familiar with reporting quarters and can plan accordingly. Another commenter requested the option to choose either a 90-day consecutive reporting period or a calendar quarter. Another commenter suggested a 60-day reporting period for 2015.

Response: We understand that some commenters may favor quarterly reporting due to the ease of planning based on a calendar quarter and to the prior requirement finalized in the Stage 2 final rule for EHR reporting periods in 2014 (77 FR 53974). However, an EHR reporting period of any continuous 90 days would still allow for providers to select and report on a quarter in the calendar year if they so choose. We disagree with the appropriateness of a 60-day EHR reporting period, and further note that a shorter EHR reporting period is not easier to meet than a longer period if the provider is fully engaged in the workflows and has the functions fully enabled. Statistically, a larger number of patient encounters allow providers a wider margin to meet the overall threshold. As the majority of providers would already have been meaningfully using their CEHRT and then attesting based on a full year EHR reporting period, or for a minimum of a 90-day EHR reporting period, these workflows should be implemented and functioning for at least that length of time. Therefore, the necessity for a shorter EHR reporting period as dictated by the need to accommodate the changes in this final rule with comment period is limited in scope to 90 days.

Comment: A commenter stated that their group practice has already gathered data for some EPs for quarters 1 and 2 and have new EPs for whom they would like to be able to report for quarter 4. The commenter requested organizations be allowed to use a different EHR reporting period for each EP.

Response: Each EP is required to individually meet the requirements of meaningful use regardless of their affiliation with a group practice. Therefore, each EP may use a separate EHR reporting period to demonstrate meaningful use and in 2015, that EHR reporting period may be any continuous 90-day period in the calendar year selected by each individual EP.

Comment: A few commenters from the EHR Incentive Programs in 2015 through 2017 proposed rule stated CMS previously requiring a full year of reporting and then subsequently removing that requirement dilutes the message to providers and sets an expectation that goals do not need to be met.

Response: We note that this perception is of concern and is not reflective of our policy goals for the program. As we stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348), the 90-day EHR reporting period is intended only to accommodate the changes to the EHR Incentive Programs in 2015 through 2017, which are in turn intended to drive toward the long-term goals outlined in the Stage 3 proposed rule.

Comment: A commenter requested CMS acknowledge the challenges associated with reporting on a full calendar year for EPs newly employed by a health system during the course of a program year, switching EHRs, system downtime, cyber-attacks, and office relocation.

A few commenters strongly recommended in the EHR Incentive Program in 2015 through 2017 proposed rule that CMS retain the 90-day attestation option for providers who change employers during the year. Furthermore, the commenters further stated they do not believe an organization can sufficiently rely upon the actions of a previous employer to complete the necessary validation, analysis, and implementation of an EHR that would satisfy CMS audit requirements. If a previous employer's data is found to be faulty, the current organization is put at risk for the data reported.

Response: We understand the commenters' concerns and note that EPs may consider applying for a hardship exception from the reduction to Medicare PFS payments based on extreme and uncontrollable circumstances. Specifically, in the case of issues related to CEHRT, situations involving technology upgrades, switching products during the year, or the decertification of a product may be reason for a provider to apply for a hardship.

EPs who are switching employment or practicing in multiple locations during an EHR reporting period may apply for a hardship exception that would be reviewed on a case-by-case basis. However, we disagree that CMS should take into account the business practices of individual EPs in establishing the requirements for the entirety of the program. It is incumbent on the individual EP to establish their own contractual or business arrangements for the purposes of attesting for the Medicare and Medicaid EHR Incentive Programs.

Comment: A commenter suggested the EHR reporting period should be at least 90 days or 3 calendar months. The

commenter suggested this would allow a provider to create a monthly report within their EHR system using their dashboard, regardless of the number of days in any given month, as long as they capture at least 90 days or 3 calendar months. As an example, the commenter suggested that an EP or administrator can run a report for October through December that would provide 92 days of data, or February through April that would provide 89 days of data.

Response: We thank the commenter for their suggestion and respectfully disagree. The EHR reporting period must be at least 90 continuous days in order to ensure that all providers are meeting at least the same minimum requirement. While a provider may choose a period longer than 90 days, they may not choose a period that is less, so the use of the designated months is not adequate. Furthermore, a 90-day period need not be tied to the beginning or end of a month. Therefore, the use of 90 days is the most appropriate for this policy as it allows flexibility for providers to choose any continuous 90-day period, or any 3-month period of at least 90 days, or any calendar year quarter of at least 90 days, without adding additional complexity. As proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348), the EHR reporting period would be any continuous 90 days for all providers in 2015. This change allows for greater flexibility in the reporting requirements.

Comment: A few commenters stated they believed the statute does not obligate CMS to require a year for reporting and believed the full year reporting requirement will discourage EPs from participation and increases risk of non-success.

Response: We agree that the statute allows discretion to specify the EHR reporting period and does not require a full year. As mentioned in our Stage 2 final rule (77 FR 53974), the more robust data set provided by a full year EHR reporting period offers more opportunity for alignment of programs, such as PQRS, than the data set provided by a shorter EHR reporting period, especially when compared across several years. We believe the full reporting year will yield data necessary to sustain and further progress the program. Furthermore, we believe, as previously noted, that the actions and workflows that support the requirements of the EHR Incentive Programs are intended to be in effect continuously, not enabled and implemented for only 90 days. Finally, we believe in the importance of alignment with and support of quality

measurement and quality improvement initiatives like Accountable Care Organizations (ACOs) and the Comprehensive Primary Care Initiative (CPCI) as well as the value based purchasing programs that require full year reporting for the efficacy of data on clinical processes and patient outcomes. Thus, our policy has been to allow a 90-day reporting period only in circumstances where a shorter reporting period is warranted to allow providers to implement program changes or to begin participation in the program.

Comment: Several commenters recommended the reporting period should be 90 days for 2016 and subsequent years, as this would greatly reduce the reporting burden. A few commenters stated that a full year of reporting in 2016 is unreasonable. Multiple commenters stated that a full year reporting period for all participants in 2016 does not adequately account for a number of real life scenarios that could cause issues with meeting the requirements, such as environmental setbacks, infrastructure problems, vendor-related difficulties, and human resource issues. Some commenters strongly recommended CMS retain the 90-day EHR reporting period for first-time attestors in the program in future years.

Response: We decline to extend the 90-day EHR reporting period to 2016 for all returning participants because we disagree that full year reporting is unreasonable. In 2012 and 2013, thousands of returning providers successfully attested to program requirements for an EHR reporting period of one full year. In addition, as noted previously, hardship exceptions may be available for providers experiencing extreme and uncontrollable circumstances. However, as proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348), all providers demonstrating meaningful use for the first time may use an EHR reporting period of any continuous 90 days in 2016, which has been the policy in past years, to support these providers beginning implementation of the program.

After consideration of the public comments received, we are finalizing a 90-day EHR reporting period in 2015 for all providers as proposed. Eligible professionals may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015. We are finalizing a 90-day

EHR reporting period in CY 2016 for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year. For all providers who have successfully demonstrated meaningful use in a prior year, we are finalizing an EHR reporting period of the full CY 2016. We have made corresponding revisions to the definition of “EHR reporting period” under § 495.4. For the payment adjustments under Medicare, we discuss the duration and timing of the EHR reporting period in relation to the payment adjustment year in section II.E.2 of this final rule with comment period.

(iii) EHR Reporting Period in 2017 and Subsequent Years

In the Stage 3 proposed rule (80 FR 16739), we proposed that beginning in 2017, and for all EPs, eligible hospitals, and CAHs, the EHR reporting period would be one full calendar year. We proposed to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. For that exception, we proposed to maintain the 90-day EHR reporting period for a provider’s first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program. We noted that the EHR incentive payments under Medicare fee-for-service (FFS) and MA (sections 1848(o), 1886(n), 1814(l)(3), 1853(l) and (m) of the Act) will end before 2017. We stated that under these proposals, EPs and eligible hospitals that seek to qualify for an incentive payment under Medicaid would have a full calendar year EHR reporting period if they are not demonstrating meaningful use for the first time.

These proposals would allow for a single EHR reporting period of a full calendar year for all providers across all settings. We proposed corresponding revisions to the definition of “EHR reporting period” under § 495.4. For the payment adjustments under Medicare, we proposed changes to the EHR reporting periods applicable for payment adjustment years in the Stage 3 proposed rule (80 FR 16774 through 16777).

Comment: Several commenters supported the proposal to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. A commenter appreciated the effort to standardize reporting timelines

to other CMS quality programs. Other commenters stated that longer reporting periods would facilitate public health reporting, as Public Health Agencies (PHAs) have more time to work with providers and their EHR vendors and developers to submit data to meet their public health measures. A few commenters indicated annual reporting has the benefit of yielding valuable data that may not necessarily be captured with a short 90-day reporting period.

Response: We appreciate the support of these comments. We believe full year reporting will allow for the collection of more comparable data and increase alignment across quality reporting programs, where measure data is typically collected over a calendar year period. The more robust data set provided by a full year EHR reporting period offers more opportunity for alignment than the data set provided by a shorter EHR reporting period, especially when compared across several years.

Comment: We received many comments opposing the full year reporting period, indicating that it is very challenging and may add administrative burdens. Commenters also indicated the following areas of concerns that could impact the ability to demonstrate a full year of meaningful use:

- EPs change in place of service (POS).
- EPs joining a practice in the middle of the year.
- Ongoing software updates (for example, ICD–10).
- Difficulty in getting data from previous places of employment.
- Not enough time for the vendors and developers to make software updates.
- Timing of the data submission.

Other commenters stated full year reporting does not allow sufficient time for these practices to identify shortcomings in their adherence to meaningful use and implement corrective actions before the next reporting period.

Response: First, we understand the commenters’ concerns and note that providers may consider applying for a hardship exception from the Medicare payment adjustments based on extreme circumstances outside the provider’s control that contribute to their inability to meet the requirements of the EHR Incentive Programs. Second, we note that the thresholds of the measures themselves are designed to provide leeway for providers to adjust workflows and implementation as necessary during the EHR reporting period. With the exception of

maintaining drug interaction and drug allergy clinical decision supports for the duration of the EHR reporting period, no measure has a threshold of 100 percent. We believe that system downtime could be expected in some cases for software or system maintenance, but providers may still meet meaningful use if they meet the threshold for each measure and are using the required CEHRT Edition for the EHR reporting period. Third, as noted previously, if a provider is fully implementing the requirements of the program, the workflows and implementation of the technology would not be limited to only 90 days, and thus a longer EHR reporting period should be feasible.

Comment: A commenter recommended shortening the reporting period from 12 months to 3 months and that CMS should consider an “incentive” for providers who report on a 6-month period or even a 12-month period. Another commenter similarly suggested reopening incentive payments for the program including providing additional monies for new participants successfully demonstrating meaningful use for a full year under the Stage 3 requirements.

Response: While we appreciate the commenter’s suggestion of additional incentives for providers, we do not have discretion to alter the timing and duration of the incentive payments under Medicare and Medicaid that are established by statute.

Comment: Some commenters also stated that the yearly reporting period also introduces problems for quality reporting and that vendors and developers have insufficient time to update and test the products, especially for new quality measures that will not be finalized under the Medicare PFS until November 1 of the previous year. Other commenters stated that vendors and developers are unlikely to be able to implement the changes made in the Medicare PFS final rule in time to deliver updated products prior to the January 1, 2018 Stage 3 deadline, and these conflicting deadlines will continue to be a problem that will impact future program years.

Response: We note that CMS quality reporting programs for EPs (for example, PQRS and Value-Based Payment Modifier) have a full year reporting or performance period and that the CQMs used for those programs require a full year of data. CMS quality reporting programs are working in partnership with the EHR developer and vendor community to streamline the annual update process to ensure the integrity of data and the effectiveness of eCQM specifications. (For further information,

we refer readers to section II.C of this final rule with comment period.)

Comment: A number of commenters requested a 90-day reporting period for providers in the first year of Stage 3 especially for any providers seeking to demonstrate the Stage 3 objectives and measures in the optional year in 2017. Some of these commenters indicated that they agree with the need for full year reporting, but believe that it is appropriate to allow a 90-day EHR reporting period when providers move to a new stage in order to mitigate issues with workflows, ensure the effective implementation of new technologies, and integrate new processes into clinical operations.

Response: We disagree that a 90-day EHR reporting period is appropriate for all providers moving to Stage 3, as we believe the lead time required for participation in 2018 is sufficient. In addition, the optional year in 2017 allows providers to work toward the Stage 3 measures and test workflows prior to their required implementation in 2018. However, we agree that the allowance of a 90-day EHR reporting period may be appropriate for providers attesting to the objectives and measures of Stage 3 in 2017. A 90-day EHR reporting period in this case would recognize the shorter time period from development of the technology to implementation for use in 2017 and a shorter time period for the necessary testing and implementation of workflows and new technologies. A 90-day EHR reporting period in 2017 would allow for further flexibility in the installation and implementation of the overall upgrade to technology certified to the 2015 Edition by spreading out the demand over a greater period of time. In addition, a 90-day EHR reporting period in 2017 for Stage 3 providers would provide a benefit by easing the transition for those providers who choose to move to Stage 3 early and will potentially make that choice more accessible for a greater number of providers. Therefore, we agree that allowing a 90-day EHR reporting period for Stage 3 providers in 2017 would support the transition to a new technology, the adoption of technology and clinical workflows, and the overall progress toward program goals.

After consideration of the public comments received, we are finalizing our proposal to require a full CY EHR reporting period for all providers (with a limited exception for new meaningful EHR users under Medicaid) beginning in CY 2017, with a modification for providers attesting to Stage 3 of meaningful use in 2017. For EPs, eligible hospitals, and CAHs that choose

to meet Stage 3 in 2017, the EHR reporting period is any continuous 90-day period within CY 2017. For all other providers, the EHR reporting period is the full CY 2017. Beginning in CY 2018, for all EPs, eligible hospitals, and CAHs (including those attesting to Stage 3 for the first time), the EHR reporting period is the full CY.

We finalize our proposal to maintain the 90-day EHR reporting period for a provider's first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program for 2017 and subsequent years.

We revised the definition of "EHR reporting period" under § 495.4 to reflect these final policies. As we noted previously and in the Stage 3 proposed rule (80 FR 16739), the incentive payments under FFS and MA (sections 1848(o), 1886(n), 1814(l)(3), 1853(l) and (m) of the Act) will end before 2017. Thus the final policies for the EHR reporting period we adopt here would apply only for EPs and eligible hospitals that seek to qualify for an incentive payment under Medicaid. For the payment adjustments under Medicare, we discuss the duration and timing of the EHR reporting period for a payment adjustment year in section II.E.2 of this final rule with comment period.

(4) Considerations in Defining Meaningful Use

(a) Considerations in Review and Analysis of the Objectives and Measures for Meaningful Use

In the Stage 3 proposed rule (80 FR 16740), we noted that for the Stage 1 and Stage 2 final rules, the requirements of the EHR Incentive Programs included the concept of a core and a menu set of objectives that a provider needed to meet as part of demonstrating meaningful use of CEHRT. In Stage 2, we also combined some of the objectives of Stage 1 and incorporated them into objectives for Stage 2. In the Stage 2 final rule (77 FR 53973), we signaled that the Stage 2 core and menu objectives would all be included in the Stage 3 proposal.

However, since the Stage 2 final rule publication, we have reviewed program performance from both a qualitative and quantitative perspective including analyzing performance rates; reviewing the adoption and use of CEHRT; and considering information gained by engaging with providers through listening sessions, correspondence, and open forums like the HIT Policy Committee. The data supported the following key points for consideration:

- Providers are performing higher than the thresholds for some of the meaningful use measures using some EHR functionalities that—prior to the Stage 1 and Stage 2 final rules—were not common place (such as the maintenance of problem lists).

- Providers in different specialties and settings implemented CEHRT and met objectives in different ways.

- Providers express support for reducing the reporting burden on measures that have "topped out."

- Providers expressed support for advanced functionality that would offer value to providers and patients.

- Providers expressed support for flexibility regarding how objectives are implemented in their practice settings.

- Providers in health systems and large group practices expressed frustration about the reporting burden of having to compile multiple reports spanning multiple stages and objectives.

Since the beginning of the Medicare and Medicaid EHR Incentive Programs in 2011, stakeholder associations and providers have requested that we consider changes to the number of objectives and measures required to meet the program requirements, including the recommendation to allow a provider to fail any two objectives, thus making all objectives "menu" objectives. We noted in the Stage 3 proposed rule (80 FR 16740) that we decline to follow these recommendations for several reasons.

First, the statute specifically requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see, for example, section 1848(o)(2)(A)(iii) of the Act). Second, there are certain objectives and measures that capture policies specifically required by the statute as core goals of meaningful use of CEHRT, such as electronic prescribing for EPs, HIE, and clinical quality measurement (see sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act). Furthermore, the statute requires that the CEHRT providers must be a "qualified EHR" as defined in section 3000(13) of the Public Health Service Act as an electronic record of health-related information on an individual that includes patient demographic and clinical health information, such as medical history and problem lists; and has the capacity to—

- Provide clinical decision support;
- Support physician order entry;
- Capture and query information relevant to health care quality; and
- Exchange electronic health information with, and integrate such

information from, other sources (see section 1848(o)(4) of the Act).

We analyzed the objectives and measures in Stage 1 and Stage 2 of the program to determine where measures are redundant, duplicative, or have topped out. "Topped out" is the term used to describe measures that have achieved widespread adoption at a high rate of performance and no longer represent a basis upon which provider performance may be differentiated. We considered redundant objectives and measures to include those where a viable health IT-based solution may replace paper-based actions, such as the Stage 2 Clinical Summary objective (77 FR 54001 through 54002). We considered duplicative objectives and measures to include those where some aspect is also captured in the course of meeting another objective or measure, such as recording vital signs.

We proposed (as discussed in sections II.B.1.b.(3) and II.C of this final rule with comment period) to reduce provider burden and simplify the program by aligning EHR reporting periods and CQM reporting. Our proposals for Stage 3 would continue the precedent of focusing on the advanced use of CEHRT and reduce the reporting burden; eliminate measures that are now redundant, duplicative, and topped out; create a single set of objectives for all providers with limited variation between EPs, eligible hospitals, and CAHs as necessary; and provide flexibility within the objectives to allow providers to focus on implementations that support their practice.

(i) Topped Out Measures and Objectives

In the Stage 3 proposed rule (80 FR 16741 through 16742), we proposed to adopt an approach to evaluate whether objectives and measures have become topped out and, if so, whether a particular objective or measure should be considered for removal from reporting requirements. We proposed to apply the following two criteria, which are similar to the criteria used in the Hospital Inpatient Quality Reporting (IQR) and Hospital Value Based Purchasing (HVBP) Programs (79 FR 50203): (1) Statistically indistinguishable performance at the 75th and 99th percentile, and (2) performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold.

Comment: A large number of commenters on the Stage 3 proposed rule are in support of the removal of reporting requirements for measures that have achieved high rates of

compliance. Some commenters wrote that this would greatly reduce the reporting burden for EPs and eligible hospitals.

Response: We thank the commenters for their support of this proposal. As we stated in the Stage 3 proposed rule (80 FR 16741), the removal of topped out measures is intended in part to focus on reduction of the reporting burden on providers for measures already achieving widespread adoption.

Comment: A few commenters stated they do not believe that performance rates alone provide a valid reason to consider a measure topped out. High performance rates on some measures among reporting EPs may be partly attributable to intensified improvement efforts motivated by the reporting opportunities. Furthermore, classifying any given measure as having a high performance rate when the Stage 2 reporting rate is less than 10 percent of all EPs is premature.

Response: Performance rates are only one factor considered in the decision to discontinue use of a measure in the Medicare and Medicare EHR Incentive Programs. Similarly, measure performance among hospitals (whether a measure is "topped out") is one of several criteria considered when determining whether to remove Hospital IQR Program measures (79 FR 50203). Multiple factors beyond performance are included in the determination of whether a measure should be considered for removal from reporting requirements.

For the 2014 EHR reporting period, more than 1,800 eligible hospitals and CAHs and 60,000 EPs attested for their performance on the Stage 2 objectives and measures. However, we did not limit our analysis to only Stage 2 providers. Instead, we looked at performance rates across the longevity of the program for providers in all levels of participation. Most of the measures identified are at exceptionally high performance among first time participants in Stage 1 as well, with little or no variation as compared to providers in 3 or more years of participation. For the Medicare and Medicaid EHR Incentive Programs, we additionally looked at measures that represent static data capture measures and measures for which the action is now automated by the EHR technology, as opposed to active measures that use the structure data to inform a clinical decision, provide patient specific education, or are used in care coordination. Once the performance on a static measure exceeds the point at which reasonable differentiation can be made among providers using CEHRT,

we believe that the active use of the data elements is more beneficial for both provider and patient than the continued requirement to measure the capture of these elements.

For further information on the performance rates for new participants, as well as quartile performance rates for individual measures, we direct readers to the CMS EHR Incentive Program Web site data and reports page.

Comment: A commenter cautioned against removing measures that may appear to be topped out but are clinically significant or focused on patient safety. Another commenter suggested that CMS consider both the pediatric population, as well as the adult population before they determine that a measure is topped out.

Response: As we stated in the Stage 3 proposed rule (80 FR 16741) and in the previous responses to comments, we believe it is appropriate to remove some measures which have reached widespread adoption. However, we agree that the analysis of these measures and their identification as topped out should take into account other factors such as clinical significance and patient safety. In the proposed rule we specifically discussed reviewing the provider performance on measures identified as redundant and duplicative measures, as this impacts the statistical likelihood that the functions of measures and the processes behind them would continue even without a requirement to report the results (80 FR 16742). For example, electronic prescribing for EPs may be considered topped out if only the performance percentiles are considered. However, we proposed to maintain this measure because it relates to clinical effectiveness and patient safety and is foundational to the program (80 FR 16747).

For the commenter mentioning pediatric versus adult populations, the EHR Incentive Programs do not include a separate set of meaningful use objectives and measures for adult populations versus pediatric populations. Nor does CMS collect individual patient data through the EHR Incentive Programs. While certain measures may include specifications related to age, CMS only collects summary-level data in the form of numerators and denominators. Therefore we are not able to compare performance on these measures for different patient populations. However, we would note that the measures we proposed to remove had significantly high performance, with providers in all specialties performing well above the required thresholds.

Comment: Another commenter is concerned that by suddenly eliminating measures, CMS may be creating uncertainty and inadvertently sending the message that sustained performance is no longer necessary. The commenter believes it is important that EPs be given proper notice of the agency's plans for eliminating measures.

Some commenters stated removing the measures may lead to EHR vendors and developers not providing metrics on the measures in reports that are used for benchmarking and internal quality improvement work. These commenters recommended that providers should continue to be required to report on all topped out measures without a threshold, where the measure would be to attest that the provider is recording the information.

Response: We notified the public of our intent to remove measures from the program through notice of proposed rulemaking and requested public comment on these changes in both the Stage 3 proposed rule and the EHR Incentive Programs in 2015 through 2017 proposed rule. In addition, as noted in the Stage 3 proposed rule (80 FR 16741), evaluation of measures and performance is common practice for CMS programs to ensure ongoing program effectiveness.

We disagree that threshold measures should be replaced with "check box" measures for each of the topped out measures as this would provide no value for measurement and is counter to the effort to reduce the reporting burden on providers. Providers who wish to independently measure the capture of a particular data element should work with their EHR developer and vendor to ensure they are receiving the most appropriate analytics for their practice and patient population—just as they would with any data element they wished to track that was not already required by the Medicare and Medicaid EHR Incentive Programs.

Comment: A few commenters stated the impact of reducing the reporting burden for meaningful use is minimal and that the burden of meeting the requirements of the EHR Incentive Programs lies in bridging clinical workflow and best practices, patient safety, technology, and program understanding.

Response: While we agree that the objectives and measures required in the program are directly correlated with clinical workflows, technology, program understanding, and patient safety, we are responding to concerns stated by a wide range and significant number of stakeholders, including the burden of

reporting requirements and complexity within the program.

After consideration of the public comments received, we are finalizing as proposed our approach for evaluating whether objectives and measures are "topped out," and if so, whether a particular objective or measure should be considered for removal from the EHR Incentive Programs.

(ii) Electronic Versus Paper-Based Objectives and Measures

In Stage 1 and Stage 2, we require or allow providers the option to include paper-based formats for certain objectives and measures, including the provision of a non-electronic summary of care document for a transition or referral, at § 495.6(j)(14)(i) for EPs and for eligible hospitals and CAHs at § 495.6(l)(11)(i), and the provision of paper-based patient education materials, at § 495.6(j)(12)(i) for EPs and § 495.6(l)(9)(i) for eligible hospitals and CAHs. For these objectives and measures, providers would print, fax, mail, or otherwise produce a paper document and manually count these actions to include in the measure calculation. We proposed to discontinue this policy for Stage 3; paper-based formats would not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use.

This does not imply that we do not support the continued use of paper-based materials in a practice setting. We strongly recommend that providers continue to provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access.

Comment: Many commenters on the Stage 3 proposed rule stated they enthusiastically support this requirement. Requiring or even allowing paper-based methods, such as faxing of summaries of care at transitions or referrals, may be hindering some providers from adopting digital technologies (for example, direct addresses) that support the overarching goal of meaningful use, which is to use technology to improve patient outcomes.

Response: We appreciate your feedback in support of eliminating paper-based methods of reporting in order to be a meaningful user in Stage 3 and we agree that limiting the focus of the program to only health IT solutions may encourage adoption as well as spurring further innovation among IT developers. As stated in the Stage 3 proposed rule (80 FR 16742) our

goal is to focus on advanced use of EHRs. While we do not in any way seek to limit the methods by which a provider may engage with a patient or share information, we do not believe that requiring providers to measure paper-based actions is consistent with the long-term goals of the program. We believe that the requirements and focus of the program should be exclusively on leveraging HIT to support clinical effectiveness and patient safety, HIE, and quality improvement.

Comment: Many commenters requested that we keep paper-based measures in place, stating that CMS should not encourage electronic processes exclusively until consumers are ready to accept them.

Response: As noted in the Stage 3 proposed rule (80 FR 16742), our policy to no longer require or allow providers to record and report paper-based actions does not imply that we do not support the continued use of paper-based materials in a practice setting. Some patients may prefer to receive a paper version of their clinical summary or may want to receive education items or reminders on paper or some other method that is not electronic. Our proposal would simply no longer require or allow providers to manually count and report on these paper-based exchanges.

Comment: Another commenter stated this proposal to eliminate paper-based formats will cause extreme hardship for providers who serve geriatric populations and will negatively impact the quality of care their elderly patients will receive. Many geriatric patients and their caretakers do not have access to internet or computers and do not have any other means of receiving electronic health information.

Response: We strongly recommend that providers continue to provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access. In some cases, this may include the continued use of non-IT based resources. However, we proposed this method would no longer be required or allowed for manual measurement in order to meet the requirements of the Medicare and Medicaid EHR Incentive Programs.

Comment: A commenter stated there must be a focus on standards to ensure that EHRs are collecting the appropriate and relevant clinical data. If printed, the electronic versions of visit summaries should be presented in a clinically relevant manner. In addition, because the commercial payer community is not

impacted by the requirements of the EHR Incentive Programs, many providers continue to prefer a paper-based information format, with electronic formats limited to practice management software. A commenter also stated that if the EHR systems do not adequately populate necessary information, paper-based formats are necessary to track actions and measure calculations.

Response: We respectfully disagree. Paper-based formats are not necessary to populate information that CEHRT systems capture. CEHRT stores data in a structured format that allows patient information to be easily retrieved and transferred. The removal of paper-based actions is intended to support the discontinuation of manual paper-based calculation and chart abstraction. If a provider's EHR is not accurately capturing and allowing for the retrieval and transfer of data, the provider should work with their EHR developer to correct the error. The provider should also ensure that all staff entering information into the EHR have the necessary training to input patient data, just as staff were previously trained to input data correctly into a paper record or administrative or billing system. We believe this will also eliminate redundancy for providers in clinical and administrative processes. As noted in the Stage 3 proposed rule, we consider redundant objectives and measures to include those where a viable health IT-based solution may replace paper-based actions (80 FR 16741).

After consideration of the public comments, we are finalizing our proposal that paper-based formats will not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use.

(iii) Advanced EHR Functions

In the Stage 3 proposed rule (80 FR 16742), we proposed to simplify requirements for meaningful use through an analysis of existing objectives and measures for Stages 1 and 2 to determine if they are redundant, duplicative, or "topped out". We noted that some of the objectives and measures which meet these criteria involve EHR functions that are required by the statutory definition of "certified EHR technology" (see section 1848(o)(4) of the Act, which references the definition of "qualified EHR" in section 3000(13) of the Public Health Service Act) which a provider must use to demonstrate meaningful use. We stated that it was our intent that the objectives and measures proposed for Stage 3 would include uses of these functions in a more advanced form. For example,

patient demographic information is included in an electronic summary of care document called a consolidated clinical document architecture (C-CDA) provided during a transition of care in the Stage 2 Summary of Care objective and measures (77 FR 54013 through 54021), which represents a more advanced use of the EHR function than in the Stage 1 and 2 objective to record patient demographic information (77 FR 53991 through 53993).

We received the following comments on this proposal and our response follows.

Comment: Many commenters applauded this proposal noting that it made no sense to require providers to track the capture of data when providers were also tracking the use of that exact same data in other objectives and measures. Providers specifically noted that items such as vital signs and smoking status were not only used in multiple other objectives (for example, they must be included in a summary of care document), but that they are also included in CQMs which allow providers more insight into the clinical relevance of the data.

Some commenters objected to removing duplicative data capture from the program—specifically citing the measures for patient demographics, structured lab results, vital signs, advance directives, and smoking status—because they believe the measures should continue to be independently captured. One commenter requested clarification on how Stage 2 measures like family health history and electronic progress reports are incorporated into Stage 3. A commenter suggested that there needs to be more clarity with respect to how those measures which are duplicative of more advanced processes are still required for use and potentially tracked through other means, such as in the common clinical data set (CCDS).

Response: As stated previously in this final rule with comment period, we note that we sought to identify the objectives and measures which measure only the capture data in a structured format without any additional requirement on the use of that data within the measure. We also note that this was an important factor in reviewing those measures which were identified as potentially topped out (section II.B.2.b.(4)(a)(i)). In other words, most measures selected for removal were both topped out and also redundant or paper-based (as discussed previously in section II.B.2.b.(4)(a)(ii)), or duplicative of more advanced use objectives. We understand some providers may still find value in independently setting goals for data

capture of structured data elements; however, we believe it is appropriate to no longer require reporting to CMS on these redundant or duplicative measures. We believe this will allow providers to focus on the use of the technology and the use of the data to support care coordination and quality improvement rather than monitoring the simple capture of that data for a measure which has already reached high capture rates.

We note that family health history is still a required data field within the definition of CEHRT at § 495.4. This means it will still be part of CEHRT available for provider use. This measure in particular was identified as having high performance, but also representing a significant burden for counting and measurement purposes. According to provider recommendations, family health history should not be recorded in an EHR in episodic fashion but should allow for linear capture as structured data that can be leveraged by more advanced functions, such as the Patient Specific Education measure under the Patient Electronic Access objective. Electronic notes are similar use cases within the CEHRT, as are the standards for advance directives and smoking status. In addition, the requirements for the fields within an electronic summary of care document, the C-CDA, include structured data elements such as demographics, medication list, medication allergy list, vital signs, and structure lab results, among others, which are required as part of the electronic summary of care document C-CDA a provider must send in conjunction with a transition of care or referral in support of effective care coordination. For further information, we refer readers to the ONC 2015 Edition Certification Criteria final rule published elsewhere in this **Federal Register**.

Comment: A commenter on the Stage 3 proposed rule stated that although it is implied, it does not appear to be clearly stated that vocabularies and standards associated with the topped out, redundant, or duplicative measures are still required for use.

Response: We did not propose to remove the required use of standards associated with structured data capture within the CEHRT. CEHRT must still include the functions and capabilities that are part of the overall definition of requirements for CEHRT for the Medicare and Medicaid EHR Incentive Programs, including LOINC standards, HL7 standards, and SNOMED standards, among others, as established in the ONC certification criteria for CEHRT. These structured data elements must also be

part of the C-CDA in an electronic exchange and the information provided to a patient through the view, download, and transmit functions of CEHRT. For further information, we refer readers to the ONC 2015 Edition Certification Criteria final rule published elsewhere in this **Federal Register**.

After consideration of the public comments received, we are finalizing our proposed approach for analyzing the objectives and measures to identify and maintain and promote the advanced use of health IT for Stage 3 of meaningful use.

(b) Considerations in Defining the Objectives and Measures of Meaningful Use for 2015 Through 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR

20354), we stated that we analyzed the existing objectives and measures of meaningful use to consider if they should be modified for the program beginning in 2015. Using the approach outlined in the Stage 3 proposed rule, we looked at the set of potential objectives and measures for inclusion in the program for 2017 and subsequent years and sought to determine if they were redundant, duplicative, or had reached a performance level considered to be topped out. We also considered the functions and standards included the technology certified to the 2014 Edition when determining if a measure is redundant or duplicative and adding a review of isolated performance rates for providers in the first year of meaningful use in addition to reviewing

quartile performance rates for topped out measures.

Our analysis of the objectives and measures of meaningful use Stage 1 and Stage 2 identified a number of measures that met the criteria as either redundant, duplicative, or topped out, with new participants consistently performing at a statistically comparable rate to returning participants. Table 2 identifies the current objectives and measures that met the criteria. Therefore, we proposed (80 FR 20355) to no longer require providers to attest to these objectives and measures as currently codified in the CFR under § 495.6 in order to meet program requirements beginning in 2015.

TABLE 2—OBJECTIVES AND MEASURES IDENTIFIED BY PROVIDER TYPE THAT ARE REDUNDANT, DUPLICATIVE, OR TOPPED OUT

Provider type	Objectives and measures	
Eligible Professional	Record Demographics	42 CFR 495.6(j)(3)(i) and (ii).
	Record Vital Signs	42 CFR 495.6(j)(4)(i) and (ii).
	Record Smoking Status	42 CFR 495.6(j)(5)(i) and (ii).
	Clinical Summaries	42 CFR 495.6(j)(11)(i) and (ii).
	Structured Lab Results	42 CFR 495.6(j)(7)(i) and (ii).
	Patient List	42 CFR 495.6(j)(8)(i) and (ii).
	Patient Reminders	42 CFR 495.6(j)(9)(i) and (ii).
	Summary of Care:	42 CFR 495.6(j)(14)(i) and (ii).
	Measure 1—Any Method	
	Measure 3—Test	
	Electronic Notes	42 CFR 495.6(j)(9)(i) and (ii).
	Imaging Results	42 CFR 495.6(k)(6)(i) and (ii).
	Family Health History	42 CFR 495.6(k)(2)(i) and (ii).
	Eligible Hospital/CAH	Record Demographics
Record Vital Signs		42 CFR 495.6(l)(3)(i) and (ii).
Record Smoking Status		42 CFR 495.6(l)(4)(i) and (ii).
Structured Lab Results		42 CFR 495.6(l)(6)(i) and (ii).
Patient List		42 CFR 495.6(l)(7)(i) and (ii).
Summary of Care:		42 CFR 495.6(l)(11)(i) and (ii).
Measure 1—Any Method		
Measure 3—Test		
eMAR		42 CFR 495.6(l)(16)(i) and (ii).
Advanced Directives		42 CFR 495.6(m)(1)(i) and (ii).
Electronic Notes		42 CFR 495.6(m)(2)(i) and (ii).
Imaging Results		42 CFR 495.6(m)(2)(i) and (ii).
Family Health History		42 CFR 495.6(m)(3)(i) and (ii).
Structure Labs to Ambulatory Providers		42 CFR 495.6(m)(6)(i) and (ii).

We noted that many of these objectives and measures include actions that may be valuable to providers and patients, such as providing a clinical summary to a patient after an office visit. We encouraged providers to continue to conduct these activities as best suits their practice and the preferences of their patient population. The removal of these measures is in no way intended as a withdrawal of an endorsement for these best practices or to discourage providers from conducting and tracking these activities for their

own quality improvement goals. Instead, we would no longer require providers to calculate and attest to the results of these measures in order to demonstrate meaningful use beginning in 2015.

Comment: The majority of commenters for the EHR Incentive Programs in 2015 through 2017 proposed rule were in support of removing the objectives and measures that are considered redundant, duplicative, or “topped out,” including patient reminders, recording vital signs,

smoking status, structured lab results, patient lists, imaging results, family health history, and demographics. Some commenters stated they agree that many of the measures no longer provided enough value to remain part of the program. Limiting the number of objectives to those that can truly impact the biggest issues facing healthcare technology is an appropriate and much needed direction.

Other commenters stated they believe this will have the effect of simplifying the EHR Incentive Programs and easing

the administrative burdens associated with the attestation process. Other commenters support the idea of encouraging providers to continue to conduct these activities if it suits their practice and the preferences of their patient population—but not be required to attest to these measures in order to meet the requirements of the program.

Response: As we stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 16741), we proposed the removal of these measures, or measures that are no longer useful in gauging performance, in order to reduce the reporting burden on providers for measures already achieving widespread adoption.

Comment: Some commenters on the EHR Incentive Programs in 2015 through 2017 proposed rule indicated some objectives still require some of the same structured data elements scheduled to be retired and some may still be of value to an organization in meeting other initiatives or regulatory requirements and are, therefore, worth retaining. A commenter disagreed with removal of the vital signs measure, as other measures may not fully capture vital sign information on all patients and keeping the measure incentivizes providers not only to collect these important data points but also to ensure that vital signs data is input into the EHR. Another commenter stated that not providing clinical summaries could have the adverse effect of decreasing patient engagement, especially if patients are not using patient portals. Some commenters indicated exempting laboratory data is especially damaging to the creation of EHRs because structured laboratory data provides the best opportunity to load results automatically into an EHR, given the degree of coding and structure, and prevents duplicate ordering. Other commenters are concerned that an EHR will not allow providers to create their own patient lists so they can assess which of their patients may require additional clinical attention. Another commenter was opposed to the removal of electronic notes, stating when providers must continually find the paper chart in order to know what is going on with the patient, it slows them down and they do not get optimal value out of an EHR.

Some commenters opposed the removal of specific objectives or measures, such as the imaging results measure, stating it should be retained as a menu set choice or as an alternate choice to implementing reporting for a second public health measure in addition to immunization reporting. Other commenters are concerned with

the removal of the family history measure because this data can be a strong indicator for preventative services. A few commenters are concerned with the removal of the record demographics measure and stated, if removed, adherence may drop and reporting will be less useful.

Response: We agree that functions and standards related to measures that are no longer required for the EHR Incentive Programs could still hold value for some providers and organizations. As stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20355), we encourage providers to continue to use the information as best suits their practice and the preferences of their patient population. The removal of these measures from the EHR Incentive Programs is not intended as a withdrawal of an endorsement of the use of the standards, the capture of the data, the implementation of best practices, or to discourage providers from conducting and tracking the information for their own quality improvement goals. Additionally, the data standards and functions will remain part of CEHRT for provider use. As part of our effort to reduce complexity, reduce reporting burden, and streamline the EHR Incentive Programs, we proposed to remove the core and menu structure established in previous rules. We do not believe the continuation of an optional menu objective for simple data capture provides better support for the standard than the support provided by requiring the inclusion of the standard in CEHRT and the use of that data within a more advanced objective.

As noted previously, we support the continued use of structured data within a certified EHR to support advanced clinical processes, care coordination, and quality improvement. The capture of this data in a structured format allows the provider to use the data for these processes and supports the efficacy of quality measurement and quality improvement. The removal of the requirement to count simple data capture allows providers to shift the focus of their use of technology to support effective use of the data.

Comment: A commenter on the EHR Incentive Programs in 2015 through 2017 proposed rule requested CMS clarify further the reasons why objectives and measures were removed.

Response: As we noted in the Stage 3 proposed rule (80 FR 16741 through 16742), we reviewed performance data submitted by providers through attestation to determine topped out measures. We applied the following

criteria to determine topped out measures: (1) Statistically indistinguishable performance at the 75th and 99th percentile, and (2) performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold. We then compared the identified measures to other meaningful use objectives that use the data in a more advanced function. We also proposed to remove measures that are paper-based for the reasons stated previously. We encourage commenters to review the performance data on our Web site under EHR Incentive Programs Objective and Measure Performance Report for additional information.³

After consideration of the public comments received, we are finalizing, as proposed, the list of objectives and measures in Table 2 identified as redundant, duplicative, or topped out and will no longer require these objectives and measures for meaningful use beginning with an EHR reporting period in 2015. The removal of these measures is reflected in the final objectives and measures adopted in the regulation text at § 495.22.

(i) Changes to Objectives and Measures for 2015 Through 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we noted that in order to implement the proposed changes to the program to align with long-term goals; there are a number of changes that must be made to other requirements of meaningful use (80 FR 20355). These changes fall into the following two major categories—

- Changes to streamline the structure in 2015 through 2017 to align with the proposed structure for Stage 3 of meaningful use in 2017 and subsequent years; and
- Changes to accommodate this shift to allow providers to demonstrate meaningful use for an EHR reporting period in 2015.

We recognized and considered the stakeholder and provider representatives' concerns in implementing the patient engagement objectives requiring patient action (see the Stage 2 final rule at 77 FR 54046 under the Health Outcomes Policy Priority “Engage patients and families in their care”), which include barriers to successful implementation of the required health IT or CEHRT functions necessary to support the measures. We proposed changes to these objectives to allow providers to focus on improvements without jeopardizing

³ CMS EHR Incentive Programs Data and Reports at www.CMS.gov/EHR_Incentive_Programs.

their ability to successfully fulfill the requirements of the EHR Incentive Programs.

(ii) Structural Requirements of Meaningful Use in 2015 Through 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we proposed to eliminate the distinction between core and menu objectives and purported that all retained objectives would be required for the program. We note that for Stage 1 providers, this means three current menu objectives would now be required; and for Stage 2 eligible hospitals and CAHs, one current menu objective would now be a required objective (80 FR 20356). These objectives are as follows:

- Stage 1 Menu: Perform Medication Reconciliation
- Stage 1 Menu: Patient Specific Educational Resources
- Stage 1 Menu: Public Health Reporting Objectives (multiple options)
- Stage 2 Menu: Eligible Hospitals and CAHs Only: Electronic Prescribing

Furthermore, we stated that the objectives and measures retained in each case for all providers would be the Stage 2 objectives and measures and

proposed to establish alternate exclusions and specifications to mitigate any additional burden on providers for an EHR reporting period in 2015 (80 FR 20356).

For the public health reporting objectives and measures, we proposed to consolidate the different Stage 2 core and menu objectives into a single objective with multiple measure options. We proposed this approach for the Stage 3 public health reporting objective because we believe it allows for greater flexibility for providers and supports continued efforts to engage providers and public health agencies in the essential data capture and information exchange that supports quality improvement, emergency response, and population health management initiatives. For further discussion of the rationale for the Stage 3 objective, we direct readers to 80 FR 16731 through 16804. For the consolidated public health reporting objective in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20366), we proposed that EPs report on any combination of two of the five available options, while eligible hospitals and CAHs report on any combination of three of the six available

options. If a provider is scheduled to attest to Stage 1 of meaningful use in 2015, we proposed to allow EPs to report on only one of the five available options outlined and the eligible hospitals or CAHs to report on any combination of two of the six available options for an EHR reporting period in 2015 (80 FR 20366).

Therefore, we proposed that the structure of meaningful use for 2015 through 2017 would be nine required objectives for EPs using the Stage 2 objectives for EPs, with alternate exclusions and specifications for Stage 1 providers in 2015. We proposed that the structure of meaningful use for 2015 through 2017 would be eight required objectives for eligible hospitals and CAHs, with alternate exclusions and specifications for Stage 1 providers and some stage 2 providers in 2015. In addition, EPs would be required to report on a total of two measures from the public health reporting objective or meet the criteria for exclusion from up to five measures; eligible hospitals and CAHs would be required to report on a total of three measures from the public health reporting objective or meet the criteria for exclusion from up to six measures.

TABLE 3—CURRENT STAGE STRUCTURE, RETAINED OBJECTIVES, AND PROPOSED STRUCTURE

	Current Stage 1 structure	Retained objectives	Proposed structure
EP	13 core objectives 5 of 9 menu objectives including 1 public health objective.	6 core objectives 3 menu objectives 2 public health objectives	9 core objectives. 1 public health objective (2 measure options).
EH/CAH	11 core objectives 5 of 10 menu objectives including 1 public health objective.	5 core objectives 3 menu objectives 3 public health objectives	8 core objectives. 1 public health objective (3 measure options).
	Current Stage 2 structure	Retained objectives	Proposed structure
EP	17 core objectives including public health objectives. 3 of 6 menu objectives	9 core objectives 0 menu objectives 4 public health objectives	9 core objectives. 1 public health objective (2 measure options).
EH/CAH	16 core objectives including public health objectives. 3 of 6 menu objectives	7 core objectives 1 menu objective 3 public health objectives	8 core objectives. 1 public health objective (3 measure options).

We received public comment on this proposal and our response follows.

Comment: Many commenters on the EHR Incentive Programs in 2015 through 2017 proposed rule relayed their support of program consolidation with transition to a single stage, as well as the removal of core and menu objectives and measures.

Other commenters believe that such changes will make it much easier for all providers to attest, for providers to know what Stage they are in, and for CMS to track providers who are in different reporting years. Some commenters stated that the transition to

a single stage of meaningful use would drastically reduce the administrative burden, provide simplicity that will benefit EHR developers and users, and facilitate meeting interoperability goals. Other commenters stated that by reducing the amount of effort that a participant has to exert—especially for measures that are already a matter of clinical routine—participants will have an experience that is significantly less intrusive.

Response: We appreciate the commenters' feedback and support for our proposal to transition to a single stage of meaningful use. In this final

rule with comment period, we are making changes to the requirements for Stage 1 and Stage 2 for 2015 through 2017 to align with the approach for Stage 3 in 2018 and subsequent years. This includes a simplified structure and focus on objectives and measures with sustainable growth potential aligned to the programs' foundational goals prior to the full implementation of Stage 3 in 2018.

Comment: Some commenters on the EHR Incentive Programs in 2015 through 2017 proposed rule stated that eliminating the core and menu structure does not mean that choice should be

eliminated from the structure of reporting. Other commenters requested that the original core and menu structure be kept in the program.

Response: The proposed removal of the core and menu structure is part of our focus to simplify the reporting requirements and decrease complexity in response to stakeholder feedback. We proposed this change to refocus program requirements on those objectives and measures that represent advanced use of CEHRT.

We disagree that the commenters' suggestion to retain a core and menu structure offers value to supporting program goals or to promoting flexibility in a meaningful way. Retaining a menu of objectives that includes topped out, redundant, or duplicative measures for the sole purpose of allowing providers to continue to choose among them is counter-productive to efforts to reduce program complexity and ease the reporting burden on providers. It also offers no benefit to CMS to continue to require reporting on measures that no longer represent a statistical value for measurement or a means of differentiating provider performance. The only other method by which a menu could be implemented would be to make formerly required objectives optional. As stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20386), we do not believe that approach supports program goals or meets our statutory duty to require more stringent measures of meaningful use over time.

Furthermore, we believe the objectives that we proposed to retain represent the functions that any provider should apply to leverage HIT in support of improved outcomes for their patients. We believe that the existing exclusions for each measure are adequate to allow flexibility for providers. Additionally, we have proposed to include alternate exclusions and specifications for Stage 1 providers in 2015 to allow them to continue the workflows they have already established for 2015 and give them time to move forward with the more advanced measures.

After consideration of public comments received, we are finalizing the changes to the structure as proposed.

(iii) Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use

We proposed (80 FR 20357) several alternate exclusions and specifications for providers scheduled to demonstrate Stage 1 of meaningful use in 2015 that would allow these providers to continue

to demonstrate meaningful use, despite the proposals to use only the Stage 2 objectives and measures identified for meaningful use in 2015 through 2017. These provisions fall into the following two major categories:

- Maintaining the specifications for objectives and measures that have a lower threshold or other measure differences between Stage 1 and Stage 2;
- Establishing exclusion for Stage 2 measures that do not have an equivalent Stage 1 measure associated with any Stage 1 objective, or where the provider did not plan to attest to the menu objective that would now be otherwise required.

For the first category, we proposed that for an EHR reporting period in 2015, providers scheduled to demonstrate Stage 1 of meaningful use may attest based on the specifications associated with the Stage 1 measure. We noted that for an EHR reporting period beginning in 2016, we proposed that all providers must attest to the specifications (including the measure thresholds) associated with the Stage 2 measure. For the second category, we proposed the alternate exclusions outlined for providers would only apply for an EHR reporting period in 2015. For an EHR reporting period in 2016, we proposed that all providers, including those who would otherwise be scheduled for Stage 1 in 2016, would be required to meet the Stage 2 specifications with no alternate exclusions.

The proposed alternate exclusions and specifications for certain objectives and measures of meaningful use for an EHR reporting period in 2015 are defined for each objective and measure in the description of each objective and measure in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20358 through 20374).

Comment: Many commenters were supportive of allowing alternate exclusions for Stage 1 providers in 2015. Some stated that if the proposal to shift to a single set of measures for 2015 were adopted, providers who were planning to attest to Stage 1 in 2015 in accordance with the current policies would certainly require accommodations. Other commenters stated that these exclusions should also be considered optional for Stage 1 providers who want to move to Stage 2 immediately. Many commenters stated that it would benefit the provider if they were able to indicate the Stage that they were scheduled to demonstrate for 2015 in the attestation system.

Response: We thank you for your support of our proposal to establish alternate exclusions and specifications

to ease the transition to a single stage of meaningful use. We proposed to accommodate eligible providers previously scheduled to demonstrate Stage 1 in 2015 by allowing alternate exclusions and specifications for certain objectives or measures. Providers scheduled to be in Stage 1 may opt to use the alternate exclusions and specifications, but they are not required to use them. The Medicare and Medicaid EHR Incentive Programs registration and attestation system will automatically identify those providers who are eligible for alternate exclusions and specifications. Upon attestation, these providers will be offered the option to attest to the Stage 2 objective and measure and the option to attest to the alternate specification or claim the alternate exclusion if available. The provider may independently select the option available to them for each measure for which an alternate specification or exclusion may apply.

Comment: A commenter requested clarification on how providers should document that they did not intend to attest to a menu objective or clarification that this is not something that will be/should be audited.

Response: We understand that intent or lack thereof may be difficult for a provider to document and will not require documentation that a provider did not plan to attest to a menu objective for the provider to claim the alternate exclusion.

Comment: A number of commenters strongly recommended that CMS keep the alternate specifications and exclusions proposed for 2015 available for providers meant to be in Stage 1 in 2016 and 2017 to allow more recent participants the same progression through the stages of the EHR Incentive Programs as those who entered the program earlier. Other commenters suggested that while the Stage 2 objectives are achievable with prior planning by 2017, retaining the alternate exclusions alternate in 2016 would allow providers to obtain and effectively implement any necessary software required to meet certain Stage 2 measures that they may not currently have in place. These commenters noted that for some objectives and measures, the need to obtain and implement CEHRT that they do not already possess would require time to ensure privacy and security protocols and patient safety measures are effectively implemented. Commenters noted this is especially true with the functions, clinical workflows, and staff training that would be required to effectively implement electronic prescribing and computerized provider order entry, which may present

a significant risk to patient safety if the technology is implemented incorrectly in order to meet an expedited timeline.

Response: We understand the commenters' concerns that meeting the Modified Stage 2 requirements may be challenging for some providers for those objectives and measures that would require the implementation of additional CEHRT modules they did not previously possess because they were not scheduled to be in Stage 2 or because they did not intend to attest to the menu objective. In general, the timing to implement these new technologies would not necessarily be prohibitive for a provider to successfully participate in 2016; however, as some commenters mentioned there are patient safety risks associated with the effective implementation of the technology and the supportive workflows which are of concern for certain objectives. To accommodate these concerns, we will allow providers who would otherwise be scheduled for Stage 1 in 2016 to claim the alternate exclusions for the Modified Stage 2 objectives and measures that would require the effective implementation of CEHRT modules for an EHR reporting period in 2016 that the provider does not currently possess. Specifically, we believe this includes measures 2 and 3 (lab and radiology orders) of the Computerized Provider Order Entry Objective for EPs, eligible hospitals, and CAHs, as well as the Electronic Prescribing Objective for eligible hospitals and CAHs. However, we do not believe this extension should include the Health Information Exchange Objective for a number of reasons. First, we have already proposed additional flexibility for that objective in 2015 through 2017 regarding the CEHRT requirement for the transmission of an electronic summary of care document. Second, we believe the threshold of 10 percent associated with the Health Information Exchange Objective and measure is achievable within a calendar year. Finally, we believe that the ability of all providers to successfully exchange health information electronically is enhanced by greater participation among providers as a whole. We also do not believe that providers who otherwise would be scheduled for Stage 1 in 2016 should be allowed to use for an EHR reporting period in 2016 the alternate specifications that we proposed for 2015, as these are only applicable for measures that already have both a Stage 1 and Stage 2 equivalent and are supported by measures using the same

CEHRT functions and standards. We direct readers to each objective in section II.B.2.a of this final rule with comment period for a full discussion of the details pertaining to the requirements for the alternate exclusions and specifications for the applicable objectives and measures.

After consideration of the public comments, we finalize the structure of the objectives and measures for the EHR Incentive Programs in 2015 through 2017 as proposed. In addition, we are finalizing as proposed the proposal for alternate exclusions and specifications for certain providers in 2015. We finalize that providers that were scheduled to demonstrate Stage 1 in 2015 or 2016 (for certain exclusions only) may choose the alternate exclusions and specifications where applicable or may attest to the modified Stage 2 objectives and measures. We finalize that EPs, eligible hospitals and CAHs that were scheduled to be in Stage 1 in 2016 may claim an alternate exclusion for an EHR reporting period in 2016 for the Computerized Provider Order Entry Objective Measures 2 and 3 (lab and radiology orders) or choose the modified Stage 2 objective and measures. We finalize that eligible hospitals and CAHs that were scheduled to be in Stage 1 in 2016 may claim an alternate exclusion for an EHR reporting period in 2016 for the Electronic Prescribing Objective or choose the modified Stage 2 Objective. For further detail, we direct readers to the individual objectives and measures for the EHR Incentive Programs in 2015 through 2017 in section II.B.2.a of this final rule with comment period. We refer readers to Table 1 in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20352) for an illustration of our policy on the prior progression of stages and whether a provider is scheduled to be in Stage 1 in 2015 or 2016.

(iv) Changes to Patient Engagement Requirements for 2015 Through 2017

As discussed in the EHR Incentive Program for 2015 through 2017 proposed rule (80 FR 20357), we proposed to make changes to two objectives that have measures related to patient engagement. We proposed to remove the threshold requirement for these two measures that count patient action in order for the provider to meet the measure. While we support patient engagement and believe that providers have a role in influencing patient behavior and supporting improved health literacy among their patients, data analysis on the measures supports concerns expressed by providers that

significant barriers exist that heavily impact a provider's ability to meet the patient action measures. Therefore, we proposed to remove the thresholds for these two measures in order to allow for further maturity of the technology, greater saturation in the market, and increased awareness among patient population. We believe this allows for the necessary time for providers to work toward patient education and the availability of these resources, as well as allowing the industry as a whole time to develop a stronger infrastructure supporting patient engagement.

There are two objectives for EPs and one objective for eligible hospitals and CAHs that specifically contain measures requiring a provider to track patient action. We proposed to modify these measures as follows:

- Patient Action to View, Download, or Transmit (VDT) Health Information
 - ++ Remove the 5 percent threshold for Measure 2 from the EP Stage 2 Patient Electronic Access (VDT) objective. Instead require that at least 1 patient seen by the provider during the EHR reporting period views, downloads, or transmits his or her health information to a third party.
 - ++ Remove the 5 percent threshold for Measure 2 from the eligible hospital and CAH Stage 2 Patient Electronic Access (VDT) objective. Instead require that at least 1 patient discharged from the hospital during the EHR reporting period views, downloads, or transmits his or her health information to a third party.
- Secure Electronic Messaging Using CEHRT
 - ++ Convert the measure for the Stage 2 EP Secure Electronic Messaging objective from the 5 percent threshold to a yes/no attestation to the statement: "The capability for patients to send and receive a secure electronic message was enabled during the EHR reporting period".

These changes are reflected in the discussion of these objectives in section II.B.2.a of this final rule with comment period. We note that these changes are intended to allow providers to work toward meaningful patient engagement through HIT using the methods best suited to their practice and their patient population. Furthermore, we note that beginning in 2018 (and optionally in 2017); providers are required to meet an objective exclusively focused on patient engagement that has an expanded set of measures and increased thresholds. (For further information on that proposed objective, we direct readers to 80 FR 16755 through 16758.)

(c) Considerations in Defining the Objectives and Measures of Meaningful Use Stage 3

After analysis of the existing Stage 1 and Stage 2 objectives and measures as described in section II.B.1.b.(4)(a) and review of the recommendations of the

HIT Policy Committee and the foundational goals and requirements under the HITECH Act, we identified in the Stage 3 proposed rule (80 FR 16743) eight key policy areas that represent the advanced use of EHR technology and align with the program’s foundational

goals and overall national health care improvement goals, such as those found in the CMS National Quality Strategy.⁴ These eight policy areas provide the basis for the proposed objectives and measures for Stage 3. They are included in Table 4 as follows:

TABLE 4—OBJECTIVES AND MEASURES FOR MEANINGFUL USE IN 2017 AND SUBSEQUENT YEARS

Program goal/objective	Delivery system reform goal alignment
Protect Patient Health Information	Foundational to the EHR Incentive Program and Certified EHR Technology.* Recommended by HIT Policy Committee.
Electronic Prescribing (eRx)	Foundational to the EHR Incentive Program National Quality Strategy Alignment.
Clinical Decision Support (CDS)	Foundational to Certified EHR Technology. Recommended by HIT Policy Committee National Quality Strategy Alignment.
Computerized Provider Order Entry (CPOE)	Foundational to Certified EHR Technology National Quality Strategy Alignment.
Patient Electronic Access to Health Information	Recommended by HIT Policy Committee National Quality Strategy Alignment.
Coordination of Care through Patient Engagement	Recommended by HIT Policy Committee National Quality Strategy Alignment.
Health Information Exchange (HIE)	Foundational to the EHR Incentive Program and Certified EHR Technology. Recommended by HIT Policy Committee National Quality Strategy Alignment.
Public Health and Clinical Data Registry Reporting	Recommended by HIT Policy Committee National Quality Strategy Alignment.

* See, for example, sections 1848(o)(2) and (4) of the Act.

In the Stage 3 proposed rule (80 FR 16743), we proposed that providers must successfully attest to these eight objectives and the associated measures (or meet the exclusion criteria for the applicable measure) to meet the requirements of Stage 3 in the Medicare and Medicaid EHR Incentive Programs. These objectives and measures include advanced EHR functions, use a wide range of structured standards in CEHRT, employ increased thresholds over similar Stage 1 and Stage 2 measures, support more complex clinical and care coordination processes, and require enhanced care coordination through patient engagement through a flexibility structure of active engagement measures.

Comment: Many commenters supported the approach for identifying the key priorities for the EHR Incentive Programs over the long term. Commenters’ opinions on the top priorities varied, with some supporting greater patient engagement, some supporting a stronger shift towards outcomes-based quality measurement and quality improvement, and others encouraging continued support of interoperability and health information exchange infrastructure. Several commenters agreed with the specific selection of high priority goals identified by CMS. Other commenters noted that the priority goals are too broad and not specific enough to outcomes and chronic disease management or that many may not be universally relevant across all patient

populations. Commenters also submitted comments on specific objectives or noted that across the board the measures associated with these objectives are not measuring improvements in patient outcomes.

Several commenters appreciated the removal of the core and menu structure of the objectives, while establishing a single set of objectives and measures in Stage 3, and believed it would reduce the program’s complexity.

Response: We thank the commenters for their input both on our selection process and on the eight key policy areas we identified as well as on the structure of Stage 3. We agree with commenters who note that a wide range of high priority health conditions, as well as specific specialties and characteristics of unique patient populations, are not explicitly recognized in our proposals or identified in the eight key policy areas. We note that we sought to establish a broad spectrum of key policy areas, which may include many varied projects, initiatives, and outcomes-based impact goals within their scope. The eight key policy areas here identified are intentionally broad in scope because, as noted in the proposed rule, we are seeking to align with overarching national health care improvement and delivery system reform goals and establish methods by which HIT can be leveraged by individual providers to support their efforts toward these key policy goals in their unique implementation.

In response to commenters who specifically cited a need to focus on outcomes and quality improvement based on outcomes measurement, we agree with this assessment. We note that the goal of the EHR Incentive Program is largely to spur the development and adoption of health HIT solutions that support these broader goals. We believe that technology itself cannot improve care coordination or patient outcomes, but the use of that technology can be a tool for providers to work toward these key policy areas. HIT can provide efficiencies in administrative processes which support clinical effectiveness, leveraging automated patient safety checks, supporting clinical decision making, enabling wider access to health information for patients, and allowing for dynamic communication between providers. That is why we proposed a set of priorities for Stage 3 that focus on these concepts. However, it is also the reason behind our efforts to align the EHR Incentive Program with the National Quality Strategy and with CMS quality measurement and quality improvement programs like PQRS, CPCI, Pioneer ACOs and Hospital IQR and HVBP programs. We welcome continued input from providers and stakeholder groups as we continue our efforts to support and promote patient-centered delivery system reform.

We note that public comments received on specific objectives and responses to comments for these objectives are included in the discussion of each objective and its

⁴ The National Quality Strategy: “HHS National Strategy for Quality Improvement in Health Care” <http://www.ahrq.gov/workingforquality/about.htm>.

associated measures in section II.B.2.b of this final rule with comment period.

After consideration of the comments received, we are finalizing our approach for setting the eight key policy areas for Stage 3 as proposed. We address the individual objectives and measures in section II.B.2.b of this final rule with comment period.

(d) Flexibility Within Meaningful Use Objectives and Measures

We proposed to incorporate flexibility within certain objectives for Stage 3 for providers to choose the measures most relevant to their unique practice setting. As a result, as part of successfully demonstrating meaningful use, providers would be required to attest to the results for the numerators and denominators of all measures associated with an objective. However, a provider would only need to meet the thresholds for two of the three associated measures. The proposed Stage 3 objectives including flexible measure options are as follows:

- **Coordination of Care through Patient Engagement**—Providers must attest to the numerators and denominators of all three measures, but must only meet the thresholds for two of three measures.
- **Health Information Exchange**—Providers must attest to the numerators and denominators of all three measures, but must only meet the thresholds for two of three measures.
- **Public Health Reporting**—EPs must report on three measures and eligible hospitals and CAHs must report on four measures.

For the objectives that allow providers to meet the thresholds for two of three measures (for example, the Coordination of Care through Patient Engagement objective and the Health Information Exchange objective), we proposed that if a provider claims an exclusion for a measure the provider must meet the thresholds of the remaining two measures to meet the objective. If a provider meets the exclusion criteria for two measures for such an objective, the provider may exclude those measures and must meet the threshold of the remaining measure to meet the objective. If a provider meets the exclusion criteria for all three measures for such an objective, the provider may exclude those measures and would still meet the objective.

Comment: We received comments supporting the flexibility proposed within certain objectives for Stage 3. Several commenters requested also allowing flexibility within other objectives not included in our proposal such as Computerized Provider Order

Entry (CPOE) and CDS in order to accommodate specialties who may have low numbers of orders or who have limited applicable CQMs to pair with a CDS. We also received recommendations to change our approach toward flexibility including allowing providers to attest to only 2 of the 3 measures for which they meet the threshold to meet the objective, allowing providers to attest to all 3 measures and meet only 1 threshold to meet the objective, and variations on those concepts.

Response: We thank the commenters and note that we did not propose flexibility for other objectives such as CPOE and CDS because we believe there are already accommodations within these objectives for specialists. For CPOE these are in the form of exclusions and for CDS providers may elect to focus their selection on high priority health conditions within their specialty if they do not believe they have adequate CQM pairings to implement. We thank those commenters who provided recommendations on the number of measures required for attestation and for the thresholds. We note that our intent to require attestation to all three is to ensure that the functions for all measures are available for provider use and to provide CMS with valuable data on performance from all providers on these measures.

After consideration of the public comments received, we are finalizing our proposal to provide flexibility within certain measures as proposed.

(e) EPs Practicing in Multiple Practices/ Locations

For Stage 3, we proposed to maintain the policy from the Stage 2 final rule (77 FR 53981) that states that to be a meaningful user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. An EP who does not conduct at least 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations equipped with CEHRT. In the Stage 2 final rule at (77 FR 53981), we defined patient encounter as any encounter where a medical treatment is provided or evaluation and management services are provided.

In addition, in the Stage 2 final rule at (77 FR 53981) we defined a practice/location as equipped with CEHRT if the record of the patient encounter that occurs at that practice/location is created and maintained in CEHRT. We

stated that this can be accomplished in the following three ways:

- CEHRT could be permanently installed at the practice/location.
- The EP could bring CEHRT to the practice/location on a portable computing device.
- The EP could access CEHRT remotely using computing devices at the practice/location.

We proposed to maintain these definitions for Stage 3.

Comment: We received a number of comments requesting clarification for providers practicing in certain settings as to how they should calculate the percentage of their patient encounters occurring in a location equipped with CEHRT. Specifically, a commenter requested guidance on how to calculate the percentage for providers who practice in a long-term care facility but for whom these patient encounters represent less than 50 percent of their total. Another commenter requested clarification on how the calculation works with regards to a hardship exception from a payment adjustment.

Response: Our policy is the same across practice settings: To be a meaningful EHR user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. Thus, EPs who practice in long-term care settings must track their outpatient encounters across their practice settings during the EHR reporting period and meet the 50 percent threshold. EPs who practice in multiple locations and lack control over the availability of CEHRT may consider applying for a hardship exception.

After consideration of the public comments received, we are finalizing our proposal to maintain this policy as finalized in the Stage 2 final rule at (77 FR 53981).

(f) Denominators

In the Stage 3 proposed rule (80 FR 16744), we note that the objectives for Stage 3 include percentage-based measures wherever possible. In the Stage 2 final rule, we included a discussion of the denominators used for the program that included the use of one of four denominators for each of the measures associated with the meaningful use objectives outlined in the Stage 2 final rule (77 FR 53982 for EPs and 77 FR 53983 for eligible hospitals and CAHs).

For EPs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients seen by the EP during the EHR reporting period.

- Office visits.
- All medication, laboratory, and diagnostic imaging orders created during the reporting period.

• Transitions of care and referrals including:

++ When the EP is the recipient of the transition or referral, first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP.

++ When the EP is the initiator of the transition or referral, transitions and referrals ordered by the EP.

For the purposes of distinguishing settings of care in determining the movement of a patient, we proposed that a transition or referral may take place when a patient is transitioned or referred between providers with different billing identities, such as a different National Provider Identifier (NPI) or hospital CMS Certification Number (CCN). We also proposed that in the cases where a provider has a patient who seeks out and receives care from another provider without a prior referral, the first provider may include that transition as a referral if the patient subsequently identifies the other provider of care.

For eligible hospitals and CAHs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period.

• All medication, laboratory, and diagnostic imaging orders created during the reporting period.

• Transitions of care and referrals including:

++ When the hospital is the recipient of a transition or referral, all admissions to the inpatient and emergency departments.

++ When the hospital is the initiator of the transition or referral, all discharges from the inpatient department, and after admissions to the emergency department when follow-up care is ordered by authorized providers of the hospital.

We proposed that the explanation of the terms "unique patients," "transitions of care," and "referrals" stated previously for EPs would also apply for eligible hospitals and CAHs, and we refer readers to the discussion of those terms in the hospital context in the Stage 2 final rule (77 FR 53983 and 53984). We proposed for Stage 3 to maintain the policy that admissions may be calculated using one of two methods (the observation services method and the all emergency

department method), as described for Stage 2 at 77 FR 53984. We stated that all discharges from an inpatient setting are considered a transition of care. We also proposed for transitions from an emergency department, that eligible hospitals and CAHs must count any discharge where follow-up care is ordered by an authorized provider regardless of the completeness of information available to the receiving provider.

Comment: We received a few comments noting that we inadvertently left out the hospital denominator termed "inpatient bed days," which was discussed in the Stage 2 final rule.

Response: We thank the commenters for their assistance and note that this was not an oversight but a deliberate omission. In the Stage 2 final rule, we stated that while inpatient bed days was a potential useful inclusion in defining discharge calculations, it was not in use for any objective or measure (77 FR 53984). As the denominators are specific to the language used in the objectives and measures, we did not include inpatient bed days in our proposal.

Comment: Multiple commenters requested clarification on when patients whose records are not maintained in CEHRT may be excluded from the denominator for a measure.

Response: Each objective includes a specific designation regarding whether the denominator or denominators for the associated measures may be limited to only those records maintain in the CEHRT. We direct readers to the definition of each objective in § 495.22 for 2015 through 2017 and § 495.24 for Stage 3, respectively.

Comment: Several commenters offered suggestions on an approach for calculation for the numerators related to any measure or objective using the "unique patient" denominator (for example, patient specific education). These commenters requested clarification for measures which are based on actions for unique patients and if they may occur before, during, or after the reporting period. Some commenters specifically mentioned FAQ 8231⁵ which specified the timing required to measure actions for the numerator for measures which do not explicitly state the timing in the numerator. The FAQ stated these actions may occur before, during or after the EHR reporting period if the EHR reporting period is less than one full year, but could not be counted

⁵ FAQ #8231 <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html> Frequently Asked Questions: EHR Incentive Programs.

if they occurred prior to the beginning of the year or after the end of the year. Commenters noted that prior interpretation used by many developers contradicted this guidance and interpreted the lack of a time distinction in the numerator to mean that the action could occur at any point and was not constrained to the EHR reporting period or even the calendar or fiscal year. Commenters requested that CMS allow a continuation of the prior interpretation until 2015 Edition technology is required in order to not force developers to change systems to a different calculation.

Response: We note that we do not agree with an interpretation of the unique patient denominator that allows for an action in previous reporting years to count in the numerator for a measure (such as the patient specific education objective and measure) in perpetuity. We believe that this not only skews the accuracy of the measure, it also is counter to the intention of establishing a benchmark of performance in each reporting period. We require these actions because we believe they should be regularly performed as part of a provider's meaningful use of CEHRT. In addition, this method of measurement suggested would cause drastic variations between providers over time based on their specialty, patient population, and frequency of repeat visits. We do, however, understand the desire to minimize the need for developers to change EHR technology already certified to the 2014 Edition or to require recertification. We address the issue of specification on timing directly in the applicable objectives in section II.B.2.a of this final rule with comment period.

Comment: One commenter requested the removal of the qualifying language regarding encounters with a new patient for the denominator for transitions and referrals for an EP. The commenter expressed concern that it was burdensome to include all new patients as a referral and that in many cases there was no referring provider initiating the first encounter with the patient.

Response: We appreciate the commenter's concern, but note that these denominators and definitions are for the purposes of defining the objectives and measures for the Medicare and Medicaid EHR Incentive Programs and that for the objectives where this language is included, we believe it is appropriate to include all new patients. Specifically, this denominator is used in objectives that relate to reconciling important patient health information including

medications the patient may be taking and any medication allergies the patient may have. We believe that it is essential that a provider include all new patient encounters (even those where there is no referring provider) in these important objectives that impact patient safety. Furthermore, we note that these definitions in the Stage 3 proposed rule at 80 FR 16744 are continuations of the Stage 2 definitions previously finalized for the Medicare and Medicaid EHR Incentive Programs in the Stage 2 final rule at 77 FR 53984.

After consideration of the public comments received, we are finalizing these denominators and the related explanations of terms as proposed.

(g) Patient Authorized Representatives

In the Stage 3 proposed rule at 80 FR 16745 we proposed the inclusion of patient-authorized representatives in the numerators of the Coordination of Care through Patient Engagement objective and the Patient Electronic Access objective as equivalent to the inclusion of the patient. We expect that patient-authorized representatives with access to such health information will always act on the patient's behalf and in the patient's best interests and will remain free from any potential or actual conflict of interest with the patient. Furthermore, we expect that the patient-authorized representatives would have the patient's best interests at heart and will act in a manner protective of the patient.

Comment: Commenters were supportive of the inclusion of a patient-authorized representative in the Stage 3 objectives and measures related to patient electronic access and patient engagement. A commenter expressed approval of our proposal to include the patient-authorized representative in the meaningful use numerators as equivalent to the patient, believing this will encourage physicians to treat the authorized representative in the same fashion as the patient. The commenter noted that this is particularly important for providers serving patient populations where a large percent have cognitive limitations or dementia and the role of the caregiver or authorized representative is critical. Another commenter noted that many patients trust and rely on their representatives to help them navigate the health care system, coordinate their care, and comply with treatment plans. Inclusion of patient-authorized representatives recognizes the importance of these individuals in the care and treatment of many patients. A number of commenters also noted that this would prove a substantial benefit to providers

caring for parents of young children and working to engage the parent using these tools in relation to the child who is their patient.

Response: We thank the commenters for their support and insight into how this policy supports the overall goals to expand the concept of patient engagement and support the communication continuum between provider and patient with the clear focus on patient-centered care.

After consideration of the public comments received, we are finalizing this policy as proposed. We direct readers to the individual objectives and measures outlined in section II.B.2.b of this final rule with comment period for further discussion of this provision within the applicable objectives and measures.

(h) Discussion of the Relationship of the Requirements of the EHR Incentive Programs to CEHRT

We proposed to continue our policy of linking each objective to the CEHRT definition and to ONC-established certification criteria. As with Stage 1 and Stage 2, EPs, eligible hospitals, and CAHs must use technology certified to the certification criteria in the ONC HIT Certification Program to meet the objectives and associated measures for Stage 3.

We received no comments specific to this proposal and are finalizing as proposed. We direct readers to the individual objectives and measures outline in section II.B.2.b of this final rule with comment period for further discussion of this provision within the applicable objectives and measures and to section II.B.3 of this final rule with comment period for discussion of the definition of CEHRT for the Medicare and Medicaid EHR Incentive Programs.

(i) Discussion of the Relationship Between a Stage 3 Objective and the Associated Measure

We proposed to continue our Stage 1 and Stage 2 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective, meeting the criteria of the measure means that the provider has met the objective in Stage 3.

We received no comments specific to this proposal and are finalizing as proposed. We direct readers to the individual objectives and measures outlined in section II.B.2.b of this final rule with comment period for further discussion of this provision within the applicable objectives and measures.

2. Meaningful Use Objectives and Measures

a. Meaningful Use Objectives and Measures for 2015, 2016, and 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20358), we proposed the following objectives and measures for EPs, eligible hospitals, and CAHs to demonstrate meaningful use for an EHR reporting period in 2015 through 2017. We noted that there are nine proposed objectives for EPs plus one consolidated public health reporting objective, and eight proposed objectives for eligible hospitals and CAHs plus one consolidated public health reporting objective. We proposed these objectives would be mandatory for all providers for an EHR reporting period beginning in 2016 and proposed to allow alternate exclusions and specifications for some providers in 2015 depending on their prior participation.

Objective 1: Protect Patient Health Information

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we proposed at 80 FR 20358 to retain, with certain modifications, the Stage 2 objective and measure for Protect Electronic Health Information for meaningful use in 2015 through 2017. In the Stage 2 final rule (77 FR 54002 through 54003), we discussed the benefits of safeguarding ePHI, as doing so is essential to all other aspects of meaningful use. Unintended and/or unlawful disclosures of ePHI could diminish consumers' confidence in EHRs and health information exchange. Ensuring that ePHI is adequately protected and secured would assist in addressing the unique risks and challenges that EHRs may present.

We note that we were inconsistent with our naming of this objective calling it "protect patient health information" and alternately "protect electronic health information". The former matches the Stage 3 Objective (section II.B.2.b.i) while the latter is what we called it in our Stage 2 final rule.

Proposed Objective: Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security

updates as necessary and correct identified security deficiencies as part of the EP, eligible hospital, or CAH's risk management process.

A review must be conducted for each EHR reporting period and any security updates and deficiencies that are identified should be included in the provider's risk management process and implemented or corrected as dictated by that process.

The HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk analysis in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>). Other free tools and resources available to assist providers include a Security Risk Assessment (SRA) Tool developed by ONC and OCR <http://www.healthit.gov/providers-professionals/security-risk-assessment-tool>.

The scope of the security risk analysis for purposes of this meaningful use measure applies to ePHI created or maintained in CEHRT. However, we noted that other ePHI may be subject to the HIPAA rules, and we refer providers to those rules for additional security requirements.

Comment: The vast majority of commenters expressed support for the inclusion of this objective. These commenters recognized the importance of protecting patient health information and agreed that this protection should consist of administrative, technical, and physical safeguards. A commenter stated that the measure is onerous for small practices because the elements of what constitutes a risk analysis are not necessarily clear. A commenter suggested an exclusion for small practices.

Another commenter noted that larger healthcare networks have a dedicated IT staff; small practices do not, making it difficult and costly to meet the standards of an annual security risk analysis and implementing security changes.

Response: We appreciate the commenters' support for the continued inclusion of this objective and measure.

We disagree that the elements of what constitutes a security risk analysis are not clear. In the proposed rule, we identified the specific requirements in the CFR and provided links to free tools and resources available to assist providers, including an SRA Tool developed by ONC and OCR. We decline to consider exclusions, including for small practices, as we

believe it is of utmost importance for all providers to protect ePHI.

We maintain that a focus on protection of electronic personal health information is necessary for all providers due to the number of breaches reported to HHS involving lost or stolen devices.

Comment: A commenter believes that these requirements are actually redundant with existing expectations for security risk assessment under HIPAA Security Rule compliance. The current HIPAA Security Rule requirement to conduct or review a security risk assessment is comprehensive and clearly requires providers to comply with all of its provisions. Thus, it seems unnecessary and overly burdensome to require attestation under the Medicare and Medicaid EHR Incentive Programs.

Response: As we have stated previously, this objective and measure are only relevant for meaningful use and this program, and are not intended to supersede what is separately required under HIPAA and other rulemaking. We do believe it is crucial that all EPs, eligible hospitals, and CAHs evaluate the impact CEHRT has on their compliance with HIPAA and the protection of health information in general.

Comment: A commenter requested clarification that only one risk assessment is required by their organization per year. The commenters noted that their organization has multiple groups of EPs with multiple 90-day reporting periods in a year.

Several commenters suggested that we incorporate the language from one of our frequently asked questions (FAQs) into the final rule—that the security risk assessment “may be completed outside of the EHR reporting period timeframe but must take place no earlier than the start of the EHR reporting year and no later than the provider attestation date.”

Many commenters suggested that we update our frequently asked questions that relate to security risk assessments.

Response: As noted in the Stage 3 proposed rule (80 FR 16746) (in which we proposed to maintain this Stage 2 objective even into Stage 3 with clarification on the timing for the requirements), the existing policy is that an analysis or review must be conducted annually for each EHR reporting period. We note that the security risk assessment is not an “episodic” item related only to a snapshot in time, but should cover the entirety of the year for which the analysis or review is conducted. Therefore, it is acceptable for the security risk analysis to be conducted outside the EHR reporting period if the

reporting period is less than one full year. However, the analysis or review must be conducted within the same calendar year as the EHR reporting period, and if the provider attests prior to the end of the calendar year, it must be conducted prior to the date of attestation. An organization may conduct one security risk analysis or review which is applicable to all EPs within the organization, provided it is within the same calendar year and prior to any EP attestation for that calendar year. However, each EP is individually responsible for their own attestation and for independently meeting the objective. Therefore, it is incumbent on each individual EP to ensure that any security risk analysis or review conducted for the group is relevant to and fully inclusive of any unique implementation or use of CEHRT relevant to their individual practice.

We intend to update our FAQs to reflect policy changes and clarifications that flow from this final rule with comment period. Prior versions of FAQs and those related to past program years will be archived and maintained for public access on our Web site at www.cms.gov/EHRIncentivePrograms.

Comment: A commenter stated that the scope of the risk assessment in the proposed rule appears to be limited to ePHI created or maintained via CEHRT. The commenter questioned whether this scope is more limited than in prior meaningful use requirements.

Response: The scope of the security risk analysis for the Medicare and Medicaid EHR Incentive Programs relates to ePHI created or maintained using CEHRT. We did not propose to change the scope of this objective and measure from the Stage 2 requirements.

Comment: Several commenters requested a national educational campaign sponsored by the federal government to help physicians ensure that they are adequately equipped to protect electronic patient information.

Response: We will continue to work with OCR and ONC on educational efforts related to protecting electronic health information. We agree that this will require ongoing education and outreach.

After consideration of public comments received, we are finalizing this objective and measure as proposed with a minor modification to adopt the title “Protect Patient Health Information” for EPs, eligible hospitals and CAHs as follows:

Objective 1: Protect Patient Health Information

Objective: Protect electronic health information created or maintained by

the CEHRT through the implementation of appropriate technical capabilities.

Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP, eligible hospital, or CAH's risk management process.

We are adopting Objective 1: Protect Patient Health Information at § 495.22(e)(1)(i) for EPs and § 495.22(e)(1)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 2: Clinical Decision Support

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20358), we proposed to retain the Stage 2 objective and measures for Clinical Decision Support (CDS) for meaningful use in 2015 through 2017 such that CDS would be used to improve performance on high-priority health conditions. This is a consolidated objective, which incorporates the Stage 1 objective to implement drug-drug and drug-allergy interaction checks. It would be left to the provider's clinical discretion to select the most appropriate CDS interventions for his or her patient population.

Proposed Objective: Use clinical decision support to improve performance on high-priority health conditions.

We proposed that CDS interventions selected should be related to four or more of the CQMs on which providers would be expected to report. The goal of the proposed CDS objective is for providers to implement improvements in clinical performance for high-priority health conditions that would result in improved patient outcomes.

Proposed Measure: In order for EPs, eligible hospitals, and CAHs to meet the objective they must satisfy both of the following measures:

- Measure 1: Implement five clinical decision support interventions related to four or more clinical quality measures

at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

- Measure 2: The EP, eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug allergy interaction checks for the entire EHR reporting period.

For the first measure, we suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency.

Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

For an EHR reporting period in 2015 only, we proposed that an EP, eligible hospital or CAH who is scheduled to participate in Stage 1 in 2015 may satisfy the following Stage 1 measure instead of the Stage 2 measure 1 as follows:

- *Proposed Alternate Objective and Measure (For Measure 1):* Objective: Implement one clinical decision support rule relevant to specialty or high clinical priority, or high priority hospital condition, along with the ability to track compliance with that rule. Measure: Implement one clinical decision support rule.

Comment: Many commenters expressed support of the Clinical Decision Support Objective in its entirety. Several noted that the inclusion of this objective in the EHR Incentive Program in 2015 through 2017 requirements ensures the continued implementation of these important supports for providers. In addition, commenters agree that it is best for CDS interventions to be implemented at the point in patient care that best enhances clinical decision making before taking an action on behalf of a patient. Some noted appreciation for the continued requirement for drug-drug and drug-allergy interaction checking. They also believe that it is a significant benefit to patient care.

A commenter was supportive of the flexibility provided by CMS and ONC in the use of homegrown alerts and for nurturing a supportive environment for those providers developing their own homegrown alerts and not deterring this type of innovation with overly onerous measure definitions or certification requirements. Many commenters

expressed that the use of CDS will have a positive impact on the quality, safety, and efficiency of care. They also supported the proposed objective and measures to use CDS to improve performance on high-priority health conditions.

Response: We greatly appreciate and thank commenters' support for this objective.

Comment: A few commenters expressed concern about the work and strain and the substantial cost involved in implementing, training, maintenance, and updating of the tools to meet the clinical decision support requirements.

A commenter expressed concerned that the requirement for every EP to have five CDS elements pertaining to his or her scope of work may be overly burdensome for large organizations with highly specialized EPs where there may be circumstances necessary to build CDS tools that would only be useful for a few individuals.

Additionally, a commenter stated there is a struggle to interpret whether or not each of our implemented features meet ONC's referential link and source attribute requirements.

Response: We recognize commenters' concerns regarding implementation of the necessary tools to meet the CDS requirements. The companion ONC standards and certification criteria final rule for the 2014 Edition certification (77 FR 54163 through 54292) as well as the 2015 Edition certification criteria in the 2015 Edition final rule published elsewhere in this **Federal Register**, provide further information regarding the standards for CDS within CEHRT. With each incremental phase of meaningful use, CDS systems progress in their level of sophistication and ability to support patient care. It is our expectation that, at a minimum, providers will select CDS interventions to drive improvements in the delivery of care for the high-priority health conditions relevant to their patient population. Continuous quality improvement requires an iterative process in the implementation and evaluation of selected CDS interventions that will allow for ongoing learning and development. In this final rule with comment period, we will consider a broad range of CDS interventions that improve both clinical performance and the efficient use of healthcare resources, and as noted in the Stage 2 final rule (77 FR 53995 through 53996), we believe sufficient CDS options exist to support providers' implementation of five total. Given the wide range of CDS interventions currently available and the continuing development of new technologies, we do not believe that any

EP, eligible hospital, or CAH would be unable to identify and implement five CDS interventions, as previously described. Therefore, we did not establish an exclusion for the first measure of this objective based on specialty in the Stage 2 final rule and we did not propose to change that policy.

Comment: A commenter suggested we eliminate the drug-drug and drug-allergy interaction checks as a topped out measure.

Other commenters requested the removal of the language requiring participants to have CDS enabled for "the entire reporting period," as it is challenging for participants to meet. A commenter suggested that we change the requirement to provide that CDS be enabled within the first 45 days of the reporting period and remain enabled throughout the reporting period.

Another commenter believes that the level of interaction checks should be determined by the organizational directives, as well as the discretion of the clinical team.

Response: We noted our belief that automated drug-drug and drug-allergy checks provide important information to advise the provider's decisions in prescribing drugs to a patient. Because this functionality provides important CDS that focuses on patient health and safety, we proposed to continue to include the use of this functionality within CEHRT as part of the objective for using CDS and maintain our belief that this function should be enabled, as previously finalized, for the duration of the EHR reporting period. We note that the provider has discretion to implement the CDS for drug-drug and drug-allergy checks in a manner that is most appropriate for their organization and clinical needs.

Comment: A commenter requested clarification on the exclusion and for similar exclusions that include the language "fewer than 100 (medication orders, office visits, etc.)." Commenters requested further clarification that the 100 would be over the course of the full year and requested confirmation that providers using a shorter reporting period should pro-rate this total for that reporting period.

Response: The policy is fewer than 100 during the EHR reporting period and this language is used consistently in both Stage 1 and Stage 2 objectives and measures that include a similar exclusion. There is no distinction based on the length of the EHR reporting period and no option to pro-rate.

Comment: Commenters additionally expressed concern about the requirement to track compliance with

CDS and recommended that we allow them to retain the freedom to use whatever forms of CDS make sense for their practice including the timing of the interventions. A commenter stated that tracking compliance puts increased emphasis on pop-up type support over other types where tracking compliance does not necessarily happen easily and noted that provider responses to some types of CDS (like creating order sets for different conditions and providing health maintenance suggestions) are not easily tracked, and not within their certified system.

Some commenters requested that CDS should be enabled to address conditions relevant to the EP's scope of practice. Others stated that children's hospitals or specialty providers should have the same level of choice that is available to adult hospitals and general practitioners, while others requested the removal of the link to CQMs completed. Still others requested that the five CDS interventions be related either to CQMs or to other metrics included in a nationally recognized quality improvement registry or a qualified clinical database registry.

One commenter on the EHR Incentive Programs for 2015 through 2017 proposed rule specifically requested clarification whether an example used in the Stage 3 proposed rule (for example, the appropriate use criteria for imaging services example at 80 FR 16750) could also be used to satisfy the CDS objective for the EHR Incentive Programs in 2015 through 2017.

Response: We appreciate the comments and note that in Stage 1, we allowed providers significant leeway in determining the CDS interventions most relevant to their scope of practice. In Stage 2 and later, we are continuing to provide the flexibility for providers to identify high-priority health conditions that are most appropriate for CDS. We expect that providers will implement many CDS interventions, and providers are free to choose interventions in any domain that is a priority to the EP, eligible hospital, or CAH.

We also agree with the commenter that providers should be allowed the flexibility to determine the most appropriate CDS intervention and timing of the CDS. The CDS measure for EPs, eligible hospitals, and CAHs allows this flexibility by allowing the implementation at a relevant point in patient care that refers to a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention. Further, many providers may associate CDS with pop-

up alerts. However, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time. We believe that the examples outlined in the Stage 3 proposed rule and further discussed in the Stage 3 objective in section II.B.2.b.iii of this final rule with comment period are applicable for CDS in general and would apply for the EHR Incentive Programs in 2015 through 2017. We refer readers to the CDS objective description in the Stage 3 proposed rule for further information (80 FR 16749 through 16750).

After consideration of the public comments received, we are finalizing the objective, measures, exclusions, and alternate objective and measure as proposed for EPs, eligible hospitals, and CAHs as follows:

Objective 2: Clinical Decision Support

Objective: Use clinical decision support to improve performance on high-priority health conditions.

Measure 1: Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Measure 2: The EP, eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug allergy interaction checks for the entire EHR reporting period.

Exclusions: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

Alternate Objective and Measure: For an EHR reporting period in 2015 only, an EP, eligible hospital or CAH who is scheduled to participate in Stage 1 in 2015 may satisfy the following in place of Measure 1:

- *Objective:* Implement one clinical decision support rule relevant to specialty or high clinical priority, or high priority hospital condition, along with the ability to track compliance with that rule.

- *Measure:* Implement one clinical decision support rule.

We are adopting Objective 2: Clinical Decision Support at § 495.22(e)(2)(i) for EPs and § 495.22(e)(2)(ii) for eligible

hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 3: Computerized Provider Order Entry

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20359), we proposed to retain the Stage 2 objective and measures for CPOE for meaningful use in 2015 through 2017, with modifications proposed for alternate exclusions and specifications for Stage 1 providers for an EHR reporting period in 2015.

Proposed Objective: Use computerized provider order entry for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional that can enter orders into the medical record per state, local, and professional guidelines.

We define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving the safety and efficiency of the ordering process. CPOE improves quality and safety by allowing clinical decision support at the point of the order, and therefore, influences the initial order decision. CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the possibility of communication and other errors.

Proposed Measures: In Stage 2 of meaningful use, we adopted three measures for this objective:

- *Measure 1:* More than 60 percent of medication orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Measure 2:* More than 30 percent of laboratory orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are

recorded using computerized provider order entry.

- *Measure 3:* More than 30 percent of radiology orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

We proposed to retain the three distinct measures of the Stage 2 objective to calculate a separate percentage threshold for all three types of orders: Medication, laboratory, and radiology. We proposed to retain exclusionary criteria for those providers who so infrequently issue an order type that it is not practical to implement CPOE for that order type. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- **Proposed Measure 1: Medication Orders**

Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 medication orders during the EHR reporting period.

- **Proposed Measure 2: Laboratory Orders**

Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

- **Proposed Measure 3: Radiology Orders**

Denominator: Number of radiology orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 radiology orders during the EHR reporting period.

An EP, through a combination of meeting the thresholds and exclusions (or both), must satisfy all three measures for this objective. A hospital must meet the thresholds for all three measures.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed alternate exclusions and alternate specifications for this objective and measures for Stage 1 providers in 2015.

Proposed Alternate Measure 1: More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP during the EHR reporting period, or created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period, are recorded using computerized provider order entry.

Proposed Alternate Exclusion for Measure 2: Provider may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.

Proposed Alternate Exclusion for Measure 3: Provider may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.

Comment: A number of commenters supported the inclusion of the objective into the proposed rule; some supported the thresholds and agreed with the alternative specifications and exclusions. A few commenters stated the thresholds for all three measures are realistically achievable if scribes and clinical staff with proper orders are allowed to perform CPOE. A few commenters appreciated the clarification around who may enter orders using CPOE for purposes of this objective. Another commenter believed that the use of CPOE in conjunction with the Clinical Decision Support for interaction checking greatly benefits patient safety initiatives and reduces medication errors.

Response: We appreciate the many comments of overall support for the CPOE objective, thresholds and alternate specifications and exclusions. We believe our explanation in the proposed rule at 80 FR 20359 of which staff may enter orders using CPOE for purposes of this objective will alleviate some of the burden associated with providers' confusion. This explanation was in response to feedback from stakeholders requesting further information.

Comment: A commenter opposed the objective indicating although there are exclusions for providers who write less than 100 orders per EHR reporting period for any of the measures, it still may be a high bar for providers new to the program or who have just completed their first year. Other commenters believe that Stage 1 participants would have difficulty meeting the objective. Another commenter requested lower thresholds related to CEHRT issues.

Response: Under our proposals for 2015, new participants in the program or those scheduled to demonstrate Stage 1 in 2015 may attest to an alternate measure 1, which is the equivalent of the current Stage 1 measure. Additionally, we proposed alternate exclusions for these providers for the measures for laboratory and radiology orders (measures 2 and 3) under CPOE. We believe the alternate specifications and exclusions provide ample flexibility for meeting the requirements in 2015.

Comment: A few commenters stated that the definition of credentialed user is difficult to isolate and varies from state to state. Another commenter stated the physician using an EHR should be able to dictate who enters orders on their behalf.

Other commenters stated they disagreed with the requirement that only credentialed staff may enter orders for CPOE, as not all medical assistants are required to be credentialed to practice. They further suggested that if a standard for medical assistant CPOE is required, then the standard should be that the medical assistant must be appropriately trained for CEHRT use (including CPOE) by the employer or CEHRT vendor in order to be counted.

Other commenters recommended that we allow medical assistants who were hired and handling the paper-based equivalent of CPOE prior to the Stage 2 final rules (September 2012), and still with the same employing organization (as of September 2012), to be referred to as "Veteran Medical Assistants" and be permitted to enter CPOE.

Another commenter proposed that the rule be revised to allow orders placed by licensed healthcare providers, medical

interns, and certified medical assistants in the numerator of the measure.

A commenter requested clarification as to whether CEHRT entries completed by scribes are eligible for CPOE.

Another commenter inquired as to whether orders entered by non-physician staff through the means of standing orders are eligible as CPOE. A commenter requested clarification on whether phone orders from physicians can be considered CPOE if they are entered at the time of the call by a licensed healthcare professional that is authorized to enter orders based on the state regulations.

Response: In the Stage 2 final rule (77 FR 53986) and in subsequent guidance in FAQ 9058,⁶ we explained for Stage 2 that a licensed health care provider or a medical staff person who is a credentialed medical assistant or is credentialed to and performs the duties equivalent to a credentialed medical assistant may enter orders. We maintain our position that medical staff must have at least a certain level of medical training in order to execute the related CDS for a CPOE order entry. We defer to the provider to determine the proper credentialing, training, and duties of the medical staff entering the orders as long as they fit within the guidelines we have proscribed. We believe that interns who have completed their medical training and are working toward appropriate licensure would fit within this definition. We maintain our position that, in general, scribes are not included as medical staff that may enter orders for purposes of the CPOE objective. However, we note that this policy is not specific to a job title but to the appropriate medical training, knowledge, and experience.

Further, we note that we did not propose to change our prior policy on allowing providers to exclude standing orders as finalized in the Stage 2 final rule at 77 FR 53986.

Finally, we believe that a circumstance involving tele-health or remote communication may be included in the numerator as long as the order entry otherwise meets the requirements of the objective and measures.

Comment: A commenter stated that CPOE does not help ensure patient safety or encourage continuity of care, which is the premise of the program. They stated "reputable labs" are not equipped to accept online orders. The commenter also indicated that interoperability issues are also a concern with meeting this measure.

⁶ CMS.gov Frequently Asked Questions #9058 [EHR Incentive Programs] <https://questions.cms.gov/faq.php?id=5005&faqId=9058>.

They stated that many specialists practice in private office settings and many do not share the same EHR system as hospitals, laboratories, and imaging facilities.

Response: We respectfully disagree with the commenter's feedback. As noted in the proposed rule, we believe CPOE improves quality and safety. For example, a CPOE for medications may trigger a clinical decision support checking for potential medication allergies or drug interactions at the point of the order and therefore, influences the appropriateness of initial order decision. In addition, we maintain our position that CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the possibility of communication and other errors. However, we note that the inclusion of the order into the patient's electronic record allows for the exchange of that information electronically, while paper-based order entry systems do not.

Comment: A commenter requested clarification on the definition of "exclusionary criteria."

Response: Exclusionary criteria are merely the exclusions listed for each of the measures. We specifically stated that we proposed to retain exclusionary criteria for those providers who so infrequently issue an order type that it is not practical to implement CPOE for that order type.

Comment: A commenter requested a combined measure for CPOE rather than the requirement that the measures be broken down by lab, meds, and imaging and stated that a 60 percent overall threshold for all orders, regardless of type, would be less burdensome to report.

Response: We respectfully disagree. As stated in the Stage 2 final rule (77 FR 53987), we believe providers implement CPOE for packages of order types which are handled similarly and so we do not believe it is appropriate to measure CPOE universally for all order types in one process. We also expressed concerns in the Stage 2 proposed rule about the possibility that an EP, eligible hospital, or CAH could create a test environment to issue the one order and not roll out the capability widely or at all. For these reasons, we finalized percentage thresholds for all three types of order medications, laboratory, and radiology, rather than one consolidated measure.

Comment: A commenter recommended that we clarify in the preamble of the final rule that EPs can exclude "protocol" or "standing orders" from the denominators of the measures under the CPOE objective, as this

explanation was provided in the preamble of the proposed rule for Stage 3, but not in the 2015 through 2017 proposed rule.

Response: We did not propose changes to our policy on “protocol” or “standing orders” from Stage 2. We reiterate from the Stage 2 final rule that we agree that this category of orders warrant different considerations than orders that are due to a specific clinical determination by the ordering provider for a specific patient. Therefore, we allow providers to exclude orders that are predetermined for a given set of patient characteristics or for a given procedure from the calculation of CPOE numerators and denominators. Note this does not require providers to exclude this category of orders from their numerator and denominator (77 FR 53986).

Comment: A commenter requested clarification defining what constitutes an “order” (for example, whether an order is equivalent to a single transaction or if each order code in the single transaction represents an individual) order. The commenter also inquired whether a laboratory panel/profile test is counted as one order.

Response: Each order that is associated with a specific code would count as one order. Multiple tests ordered at the same time count individually if they fall under a different order code. For example, a laboratory panel, which consists of one order code but multiple tests, would only count as one order for the purposes of CPOE. If those tests were ordered individually with each having its own order code, each test would count as an order.

Comment: Several commenters requested that for CPOE measure 2 lab orders, we modify the exclusion criteria to include circumstances where there are no receiving centers for electronic radiology orders or lab orders in case there are no local or regional imaging centers that are set up to receive or transmit CPOE. Another commenter believed there should be an additional exclusion for measure 2 to address instances in which the lab does not want to connect electronically due to the low number of lab orders submitted by the physician. One commenter stated CPOE measures are not relevant or valuable for physician office or outpatient settings and should be limited only to inpatient settings such as hospitals.

Some commenters stated that the CPOE objective should be considered topped out.

Response: We respectfully disagree with the commenters. CPOE is the entry

of the order into the patient’s EHR that uses a specific function of CEHRT. CPOE does not otherwise specify how the order is filled or otherwise carried out. Therefore, whether the ordering of laboratory or radiology services using CPOE in fact results in the order being transmitted electronically to the laboratory or radiology center conducting the test does not affect a provider’s performance on the CPOE measures. CPOE is a step in a process that takes place in both hospital and ambulatory settings, and we continue to believe it is relevant to both settings.

Additionally, we note that when we analyzed attestation data from 2011 through 2013, provider performance on the CPOE measures is high, but high performance is not the only consideration in determining whether to retain an objective or measure in the program. We also review provider performance across varying levels of participation, the variance between provider types at different quartiles, stakeholder feedback on the potential value add of the objective and measure, and other similar considerations. Based on these factors, we believe the CPOE objective should be maintained in the program as it promotes patient safety and clinical efficiency. In addition, we believe there is room for significant improvement on measure performance.

Comment: A commenter suggested replacing “radiology orders” with “imaging orders” to better align with the Stage 3 objective.

Response: We appreciate the feedback and suggestion. In the proposed rule, we sought to make changes to the requirements for Stage 1 and Stage 2 of meaningful use for 2015 through 2017 to align with the approach for Stage 3. However, as stated in the proposed rule, we also sought to avoid proposing new requirements that would require changes to the existing technology certified to the 2014 Edition certification criteria, and therefore, retained the three measures of the current Stage 2 objective (medication, laboratory, and radiology) as finalized in Stage 2 (77 FR 53987).

Comment: A commenter specifically requested an exclusion for providers who are using a 90-day reporting period of less than 25 medication orders for the 90-day reporting period.

Response: We decline to change the exclusion criteria. The policy is fewer than 100 orders during the EHR reporting period and this language is used consistently in both Stage 1 and Stage 2 objectives and measures that include a similar exclusion. There is not a distinction based on the length of the EHR reporting period.

After consideration of public comments received, we are finalizing the alternate exclusions and specifications with the following modifications based on the final policy we adopted in section II.B.1.b.(4)(b)(iii) of this final rule with comment period. We note that providers who would otherwise have been scheduled for Stage 1 in 2016 may be required to implement technology functions for certain Stage 2 measures if they do not already have these functions in place because there is no Stage 1 equivalent to the Stage 2 measure. In certain cases, the improper implementation of these functions could represent a patient safety issue and therefore we are finalizing an alternate exclusion in 2016 in order to allow sufficient time for implementation in these circumstances. The Stage 2 CPOE objective measure for lab orders and the measure for radiology orders both require functions that a provider who was expecting to be in Stage 1 in 2016 may not be able to safely implement in time for an EHR reporting period in 2016. Therefore a provider may elect to exclude from these two measures for an EHR reporting period in 2016 if they were previously scheduled to be in Stage 1 in 2016.

We are finalizing the objective, measures, exclusions and alternate specifications and exclusions for EPs, eligible hospitals, and CAHs as follows:

Objective 3: Computerized Provider Order Entry

Objective: Use computerized provider order entry for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional that can enter orders into the medical record per state, local, and professional guidelines.

Measure 1: More than 60 percent of medication orders created by the EP or by authorized providers of the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Denominator:* Number of medication orders created by the EP or authorized providers in the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of orders in the denominator recorded using CPOE.

- *Threshold:* The resulting percentage must be more than 60 percent in order for an EP, eligible hospital or CAH to meet this measure.

- *Exclusion:* Any EP who writes fewer than 100 medication orders during the EHR reporting period.

Measure 2: More than 30 percent of laboratory orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Denominator:* Number of laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of orders in the denominator recorded using CPOE.

- *Threshold:* The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

- *Exclusion:* Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

Measure 3: More than 30 percent of radiology orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Denominator:* Number of radiology orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of orders in the denominator recorded using CPOE.

- *Threshold:* The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

- *Exclusion:* Any EP who writes fewer than 100 radiology orders during the EHR reporting period.

Alternate Exclusions and Specifications

- *Alternate Measure 1:* For Stage 1 providers in 2015, more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP during the EHR reporting period, or created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the

EHR reporting period, are recorded using computerized provider order entry.

Alternate Exclusion for Measure 2: Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016.

Alternate Exclusion for Measure 3: Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016.

We are adopting the Objective 3: Computerized Provider Order Entry at § 495.22(e)(3)(i) for EPs and § 495.22(e)(3)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 4: Electronic Prescribing

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20360), we proposed to retain the Stage 2 objective and measure for Electronic Prescribing (eRx) for EPs, as well as for eligible hospitals and CAHs, for meaningful use in 2015 through 2017. We note that the Stage 2 objective for eligible hospitals and CAHs is currently a menu objective, but we proposed the objective would be required for 2015 through 2017, with an exception for Stage 1 eligible hospitals and CAHs for an EHR reporting period in 2015.

(A) *Proposed EP Objective:* Generate and transmit permissible prescriptions electronically (eRx).

As noted in the Stage 2 final rule at 77 FR 54035, the use of electronic prescribing has several advantages over having the patient carry the prescription or the provider directly faxing handwritten or typewritten prescriptions to the pharmacy. These advantages include: Providing decision support to promote safety and quality in

the form of adverse interactions and other treatment possibilities; efficiency of the health care system by alerting the EP to generic alternatives or to alternatives favored by the patient's insurance plan that are equally effective; reduction of communication errors; and automatic comparisons of the medication order to others the pharmacy or third parties have received for the patient. We proposed to maintain these policies in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20361).

Proposed EP Measure: More than 50 percent of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

We proposed to retain the exclusion introduced for Stage 2 that would allow EPs to exclude this objective if no pharmacies within 10 miles of an EP's practice location at the start of his/her EHR reporting period accept electronic prescriptions.

We also proposed to retain the exclusion for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period; or Number of prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Threshold: The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

Exclusions: Any EP who:

- Writes fewer than 100 permissible prescriptions during the EHR reporting period; or

- Does not have a pharmacy within his or her organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed that for an EHR reporting period in 2015, EPs scheduled to demonstrate Stage 1 of meaningful use may attest to the specifications and threshold associated with the Stage 1 measure. We note that for an EHR

reporting period beginning in 2016, all EPs must meet the specifications and threshold for the retained Stage 2 measure in order to successfully demonstrate meaningful use.

Proposed Alternate EP Measure: More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.

We proposed no alternate exclusions for this EP objective.

Comment: We received a number of comments in support of this objective including commenters who stated that clinicians support electronic prescribing if it is efficient and does not interfere with workflows. Of those who supported the objective, most believe that electronic prescribing has clear patient and provider benefits, specifically with helping to reduce prescription errors. Some commenters also supported the proposal to continue to exclude over-the-counter medications from the definition of prescription for the purposes of the electronic prescribing objective. Commenters specifically stated support, noting that the use of electronic prescribing will reduce the number of prescription drug related adverse events, deter the creation of fraudulent prescriptions, and decrease the opportunity for prescription drug misuse and abuse. Finally, a commenter noted that the inclusion of the drug formulary query will support CMS' efforts to reduce the financial burden to the patient.

Response: We thank the commenters for their insight and support of this objective.

Comment: One topic of concern expressed by commenters was how controlled substances would be addressed in this final rule with comment period given that there are certain state restrictions on how providers can prescribe controlled substances. Commenters stated that in the past, previous mandates stated that prescriptions for controlled substances were required have to be written, not electronically prescribed. Many commenters indicated they believe the inclusion of controlled substances should remain optional and depend on whether or not the state allows the electronic prescription submission of these types of drugs. However, other commenters noted that many states now allow controlled substances to be electronically prescribed either for all prescriptions or for certain circumstances and types of drugs. These commenters noted that controlled substances should be included where feasible, as the inclusion would reduce the paper-based prescription process often used for such prescriptions, as

long as the inclusion of these prescriptions are permissible under in accordance with state law.

Response: We appreciate the feedback on the inclusion of controlled substances and agree that at present this should remain an option for providers, but not be required. As the commenters note, many states have varying policies regarding controlled substances and may address different schedules, dosages, or types of prescriptions differently. Given these developments with states easing some of the prior restrictions on electronically prescribing controlled substances, we believe it is no longer necessary to categorically exclude controlled substances from the term "permissible prescriptions." Therefore the continued inclusion of the term "controlled substances" in the denominator may no longer be an accurate description to allow for providers seeking to include these prescriptions in the circumstances where they may be included. We will define a permissible prescription as all drugs meeting our current Stage 2 definition of a prescription (77 FR 53989) with a modification to allow the inclusion of controlled substances where feasible and allowed by law as proposed in Stage 3 (80 FR 16747) in the denominator of the measure. We will no longer distinguishing between prescriptions for controlled substances and all other prescriptions, and instead will refer only to permissible prescriptions (consistent with the definition for Stage 3 at Section II.B.2.b.ii). Therefore, we are changing the measure for this objective to remove the term controlled substances from the denominator and instead changing the denominator to read "permissible prescriptions". We note this is only a change in wording and does not change the substance of our current policy for Stage 2—which providers have the option, but are not required, to include prescriptions for controlled substances in the measure—which we will maintain for 2015 through 2017. For the purposes of this objective, we are adopting that prescriptions for controlled substances may be included in the definition of permissible prescriptions where the electronic prescription of a specific medication or schedule of medications is permissible under state and federal law.

Comment: A number of providers commented on the inclusion of the query for the drug formulary, noting that this process takes time, interrupts provider workflows, is burdensome for providers to conduct for patients who are uninsured, and often requires additional paperwork or manual

processing in order to comply with the requirement that each prescription must complete a query in order to count in the numerator. Some providers noted a gap in the CEHRT function for this measure.

Response: If no formulary is available for a prescription, the provider may still count the patient in the numerator for the measure. However, we understand that the formulary query may prove burdensome in some instances, especially when it requires additional action beyond the automated function in CEHRT. We believe that the query of a formulary can provide a benefit, and our long-term vision is the progress toward fully automated queries using universal standards in real time. In order to balance the potential benefit of this function with the current burden on providers, we provide the following guidance on how providers may count the query of a formulary. Providers may count a patient in the numerator where no formulary exists to conduct a query, providers may also limit their effort to query a formulary to simply using the function available to them in their CEHRT with no further action required. This means that if a query using the function of their CEHRT is not possible or shows no result, a provider is not required to conduct any further manual or paper-based action in order to complete the query, and the provider may count the prescription in the numerator.

After consideration of the public comments received, we are finalizing changes to the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. We are finalizing that these prescriptions may be included in the definition of "permissible prescriptions" at the providers discretion where allowable by law. We are modifying the measure language to maintain "permissible prescriptions" and remove the "or all prescriptions" language and changing the denominator to read "Number of permissible prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period" in accordance with this change. We are finalizing the alternate specifications for providers scheduled to demonstrate Stage 1 of meaningful for an EHR reporting period in 2015 as proposed.

We are finalizing the objective, measure, exclusions and alternate specifications for EPs as follows:

Objective 4: Electronic Prescribing

EP Objective: Generate and transmit permissible prescriptions electronically (eRx).

Measure: More than 50 percent of permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of permissible prescriptions written during the EHR reporting period for drugs requiring a prescription in order to be dispensed.

- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

- *Exclusions:* Any EP who:
 - Writes fewer than 100 permissible prescriptions during the EHR reporting period; or
 - Does not have a pharmacy within his or her organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period

Alternate Specifications: Alternate EP Measure: For Stage 1 providers in 2015, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.

We are adopting Objective 4: Electronic Prescribing at § 495.22(e)(4)(i) for EPs. We further specify that in order to meet this objective and measure, an EPm must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

(B) *Proposed Eligible Hospital/CAH Objective:* Generate and transmit permissible discharge prescriptions electronically (eRx).

In the Stage 2 final rule at 77 FR 54035, we describe how the use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the hospital generates the prescription electronically, CEHRT can provide support for a number of purposes, such as: Promoting safety and quality in the form of decision support around adverse interactions and other treatment possibilities; increasing the efficiency of the health care system by

alerting the EP to generic alternatives or to alternatives favored by the patient's insurance plan that are equally effective; and reducing communication errors by allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient. This allows for many of the same decision support functions enabled at the generation of the prescription, but with access to potentially greater information. For this reason, we continue to support the use of electronic prescribing for discharge prescriptions in a hospital setting (80 FR 20361).

Proposed Eligible Hospital/CAH Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

We proposed to retain the exclusion that would allow a hospital to exclude this objective if there is no internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- *Denominator:* Number of new, changed, or refill prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.

- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically.

- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

- *Exclusion:* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed that eligible hospitals and CAHs scheduled to report on Stage 1 objectives for an EHR reporting period in 2015 may claim an exclusion for the Stage 2 eRx measure as there is not an equivalent Stage 1 measure defined at 42 CFR 495.6. We further proposed that eligible hospitals and CAHs scheduled to report Stage 2 objectives for an EHR

reporting period in 2015 that were not intending to attest to the eRx menu objective and measure may also claim an exclusion.

Proposed Alternate Eligible Hospital/CAH Exclusion: Provider may claim an exclusion for the eRx objective and measure for an EHR reporting period in 2015 if they were either scheduled to demonstrate Stage 1, which does not have an equivalent measure, or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx menu objective for an EHR reporting period in 2015.

We proposed no alternate specifications for this eligible hospital and CAH objective.

Comment: Commenters were divided in terms of opposition to or support of the proposed objective for eligible hospitals and CAHs. Those in support expressed agreement with the concept of the requirement that discharge prescriptions be transmitted electronically, citing improvements in patient safety and reducing medication errors. Those in opposition predominantly cited concern over their ability to adopt the necessary technology by 2016.

A commenter noted that electronic prescribing would cause medication errors because the hospital often makes numerous changes to a patient's prescription at the time of discharge, and incorrect prescriptions (with the wrong medication or dosage) written on paper can simply be torn up rather than requiring a new prescription to be sent and causing confusion for the patient. Other commenters also stated similar scenarios related to current workflows, which would need to be changed in order to comply with electronic prescribing requirements.

Response: We thank the commenters for their input and consideration of this proposal. We agree that the successful implementation of electronic prescribing for eligible hospitals and CAHs would require changes to technology implementation and workflows. However, we believe the opportunity for efficiencies and improvements in patient safety outweigh these concerns. We will finalize the proposed objective and measure for eligible hospitals and CAHs. However, we will maintain the alternate exclusion through 2016 in order to allow adequate time to update systems and workflows to support successful and safe implementation.

Comment: A number of commenters on the hospital measure also noted concerns over the formulary and controlled substances. As commenters on the EP objective noted, there are

currently challenges involved in effectively completing a query of a drug formulary universally which may cause an additional burden on providers. Commenters also noted that the ability to include or exclude controlled substances should be continued but made more flexible to reflect the changes regarding the allowance and feasibility of electronic prescribing for these medications. Some commenters noted this would be especially important for eligible hospitals and CAHs serving patients in a wide geographic region which may overlap multiple jurisdictions. These commenters noted that a change around the language to make it more flexible would allow them to include prescriptions for controlled substance based on an organizational policy that addressed any potential discrepancies. Other commenters requested clarification on the approach for internal pharmacies and drugs dispensed on site.

Finally, other commenters provided feedback on the request for comment regarding refill prescriptions and continued medications and whether the measure language should be modified to only mention “new prescriptions” or “new or changed prescriptions” rather than the proposed continuation of including new, changed, and refilled prescriptions. The vast majority of commenters did not support including refilled prescriptions noting that these prescriptions should be included and monitored by the original prescriber. Commenters were divided on whether to include or exclude changed prescriptions. Some noting, again, that changed prescriptions should be monitored by the original prescriber while others noted that the change constitutes accountability for the prescription by the eligible hospital.

Response: We agree these concerns are applicable for both the EP and the eligible hospital/CAH measures. The guidance we provided above regarding how providers may count the query of a formulary for the EP measure is also applicable for the eligible hospital/CAH measure. For controlled substances, based on public comment received we are finalizing similar changes to the denominator for the eligible hospital objective as were adopted for the EP objective to allow for the inclusion or exclusion of these prescriptions at provider discretion where allowable by law. We further note that prescriptions from internal pharmacies and drugs dispensed on site may be excluded from the denominator. Finally, we thank the commenters for their insight and will exclude refill prescriptions but maintain

other prescription types. We agree with the rationale stated by commenters; however we note that many EHRs may be programmed to automatically include these prescriptions and a change in the definition could cause unintended negative consequences for EHR system developers and providers if the change required significant modifications to the software. Therefore we will modify the measure language to remove the requirement for refill prescriptions, but we will allow providers discretion over including or excluding these prescriptions rather than requiring providers to exclude them.

After consideration of the public comments received, we are modifying our proposal and finalizing changes to the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. We are finalizing that these prescriptions may be included in the definition of “permissible prescriptions” at the providers discretion where allowable by law. We are modifying the denominator to read “Number of permissible new, changed, or refill prescriptions written for drugs requiring a prescription in order to be dispensed for patients discharged during the EHR reporting period” in accordance with this change.

Finally, we proposed that some of the Stage 2 objectives and measures do not have an equivalent Stage 1 measure and so for 2015 we proposed to allow providers to exclude from these measures. However, the eligible hospital electronic prescribing objective was included in this policy for both Stage 1 providers and Stage 2 providers in 2015 because it was previously a menu measure so many Stage 2 providers may not be able to meet the measure in 2015 if they had not prepared to do so. As noted in section II.B.1.b.(4)(c)(iii), based on public comment we determined to also allow alternate exclusions in 2016 for certain measures. We determined this to be necessary because, for certain measures providers may not have the specific CEHRT function required to support the measure if they were not prepared to attest to that measure in 2015. These providers may not be able to successfully obtain and fully and safely implement the technology in time to succeed at the measure for an EHR reporting period in 2016. In the case of electronic prescribing, accelerating the implementation of the technology in a short time frame could present a patient safety risk, and so therefore for the eligible hospital objective we are finalizing an alternate exclusion in 2016 for eligible hospitals scheduled for Stage

1 or Stage 2 in 2016. We believe this change will provide the time necessary to safely implement the technology for eligible hospitals and CAHs. Therefore, we are finalizing the alternate exclusion for providers scheduled to demonstrate meaningful for an EHR reporting period in 2015 with an extension of the exclusion into 2016.

We are finalizing the objective, measure, exclusions, and alternate exclusion for eligible hospitals and CAHs as follows:

Objective 4: Electronic Prescribing

Eligible Hospital/CAH Objective: Generate and transmit permissible discharge prescriptions electronically (eRx).

Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of new or changed permissible prescriptions written for drugs requiring a prescription in order to be dispensed for patients discharged during the EHR reporting period.

- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically.

- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

- *Exclusions:* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

Alternate Exclusion: Alternate Eligible Hospital/CAH Exclusion: The eligible hospital or CAH may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2015 if they were either scheduled to demonstrate Stage 1, which does not have an equivalent measure, or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx objective for an EHR reporting period in 2015; and, the eligible hospital or CAH may claim an exclusion for the eRx objective and measure for an EHR reporting period in 2016 if they were either scheduled to demonstrate Stage 1 in 2016 or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx objective for an EHR reporting period in 2016.

We are adopting the Objective 4: Electronic Prescribing at § 495.22(e)(4)(ii) for eligible hospitals

and CAHs. We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 5: Health Information Exchange

For Objective 5: Summary of Care (here retitled to Health Information Exchange), we proposed to retain only the second measure of the existing Stage 2 Summary of Care objective for meaningful use in 2015 through 2017 (80 FR 20361) and directed readers to the full description in the Stage 2 final rule at 77 FR 54013 through 54021.

Proposed Objective: The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

Proposed Measure: The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care that—(1) Uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

We proposed to retain an updated version of the second measure of the Stage 2 Summary of Care objective with modifications based on guidance provided through CMS responses to frequently asked questions we have received since the publication of the Stage 2 final rule. We proposed to retain this measure for electronic transmittal because we believe that the electronic exchange of health information between providers would encourage the sharing of the patient care summary from one provider to another and important information that the patient may not have been able to provide. This can significantly improve the quality and safety of referral care and reduce unnecessary and redundant testing. Use of common standards in creating the summary of care record can significantly reduce the cost and complexity of interfaces between different systems and promote widespread exchange and interoperability.

The proposed updates to this measure reflect stakeholder input regarding operational challenges in meeting this measure, and seek to increase flexibility

for providers while continuing to drive interoperability across care settings and encouraging further innovation. Previously, the measure specified the manner in which the summary of care must be electronically transmitted stating: Providers must either—(1) Electronically transmit the summary of care using CEHRT to a recipient; or (2) where the recipient receives the summary of care record via exchange facilitated by an organization that is a Nationwide Health Information Network (NwHIN) Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We proposed to update this measure to state simply that a provider would be required to create the summary of care record using CEHRT and transmit the summary of care record electronically.

To calculate the percentage of the measure, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP's or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Threshold: The percentage must be more than 10 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed that providers scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may claim an exclusion for Measure 2 of the Stage 2 Summary of Care core objective because there is not an equivalent Stage 1 measure.

Proposed Alternate Exclusion: Provider may claim an exclusion for the measure of the Stage 2 Summary of Care objective, which requires the electronic transmission of a summary of care document if, for an EHR reporting period in 2015, they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

We proposed no alternate specifications for this objective.

Comment: Many commenters supported our efforts towards interoperability and continuity of care. Commenters' general opposition to our original Stage 2 efforts included concerns about building the direct tool into existing systems being difficult and expensive, as well as the lack of receiving facilities capable of direct exchange. Commenters provided a number of general recommendations, including suggestions for keeping data private, allowing providers more freedom regarding which information is included in the summary of care documents, and permitting more alternative technologies to meet the measure. In addition, many commenters expressed the need for a more coordinated effort towards data integration on a national scale, such as a centralized data registry and national standards for interaction and interfacing with data through CEHRT.

Response: We appreciate the comments provided and the wide range of subjects raised in the comments. We agree with the general sentiment that a continued push for improved infrastructure, flexibility, and interoperability among data systems is necessary and appreciate the continued efforts of providers to play a role in this ongoing effort to modernize health care information systems and promote better care coordination through electronic health information exchange.

Comment: Some commenters expressed a general confusion that there was not a list of the required data elements for the C-CDA in the proposed rule. Some commenters expressed an assumption that because we did not restate the previously finalized list, we are allowing providers to determine the data and information to include in the summary of care document. Other commenters noted that in the numerator discussion for the summary of care, the problem list, medication list and medication allergy list requirement is not reflected, but in subsequent text in the proposed rule the required inclusion of these data elements is clearly identified. These commenters suggest clarification of this point.

Finally, some commenters asked if the omission was intentional and if we intended that the data elements would still be available for providers to use discretion on a case-by-case basis. Other commenters did not express confusion about the requirement, but did not that some flexibility would be welcome as their trading partners are often overwhelmed by the amount of unnecessary information they receive, especially in relation to extensive

laboratory test results. The commenters suggested that allowing individual providers some flexibility to determine what is important and relevant to send to the next provider in care would allow receiving providers to process and use the information more effectively.

Response: First, we note that we did not intend to cause this confusion. As stated in the EHR Incentive Program in 2015 through 2017 proposed rule at (80 FR 20361) we proposed to maintain the second measure of the Stage 2 Summary of Care Objective with certain modifications. For efficiency and to reduce the overall length of the proposed rule, we focused our discussion on the proposed modifications and referenced the full description of the measure in the Stage 2 final rule at 77 FR 54013 through 54021. The only modifications that we intended to make were those that we expressly discussed, and unless we indicated otherwise, our intention was to maintain the existing Stage 2 policies for the measure. This includes maintaining the requirements for the data elements included in the summary of care document at 77 FR 54016 as follows:

“All summary of care documents used to meet this objective must include the following information if the provider knows it:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Encounter diagnosis
- Immunizations.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI).
- Smoking status.
- Functional status, including activities of daily living, cognitive and disability status.
- Demographic information (preferred language, sex, race, ethnicity, date of birth).
- Care plan field, including goals and instructions.
- Care team including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider.
- Discharge instructions (Hospital Only)
- Reason for referral (EP only)

In circumstances where there is no information available to populate one or more of the fields listed previously, either because the EP, eligible hospital, or CAH can be excluded from recording such information (for example, vital signs) or because there is no information

to record (for example, laboratory tests), the EP, eligible hospital, or CAH may leave the field(s) blank and still meet the objective and its associated measure.

In addition, all summary of care documents used to meet this objective must include the following in order to be considered a summary of care document for this objective:

- Current problem list (providers may also include historical problems at their discretion),
- Current medication list, and
- Current medication allergy list.

An EP or hospital must verify these three fields for current problem list, current medication list, and current medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care document.”

We intend to maintain this policy of the required data elements for the C-CDA as previously finalized. However, we do understand provider concern over the ability to exercise some discretion over the amount of data transmitted, and as noted in the Stage 3 proposed rule (80 FR 16760) we recognize there may be reasons to apply a policy of determining clinical relevance for the amount of data in the lab results field and clinical notes field which should be included in the summary of care document.

Specifically, it may be beneficial for a provider to limit the lab results transmitted in the record of an extended hospital stay to those which best represent the patient status upon admission, any outliers or abnormal results, and the patient status upon discharge. Further, we note that this is only one example and other definitions of clinical relevance for lab results may apply in other clinical settings and for other situations. We are therefore adopting a similar policy for this measure as the one outlined for Stage 3; however, we are limiting this policy to lab results. We are therefore requiring that a provider must have the ability to send all laboratory test results in the summary of care document, but that a provider may work with their system developer to establish clinically relevant parameters based on their specialty, patient population, or for certain transitions and referrals which allow for clinical relevance to determine the most appropriate results for given transition or referral. We further note that a provider who limits the results in a summary of care document must send the full results upon the request of the receiving provider or upon the request by the patient. For discussion of this proposal in relation to the Stage 3

objective in this final rule with comment period we direct readers to section II.B.2.b.vii.

Comment: Many commenters supported the modified objective removing the 50 percent measure for providing a summary of care record by any means, as well as the measure's widening of the pathways acceptable for transmitting Summary of Care records. These commenters noted that the relaxation of requirements for manual transmission will allow them to better tailor the contents of the summary of care document to the transport mechanism and will, in fact, encourage the electronic adoption because of the ease of obtaining a full range of information on a patient as compared to non-electronic transport mechanisms.

Response: As noted previously, the general movement away from requiring reporting on paper-based measures is intended to allow providers to focus efforts on the use of CEHRT to support health information exchange. We agree that limiting the EHR Incentive Program objectives and measures exclusively to electronic transmissions while simultaneously expanding the options by which such exchange may occur will allow developers, providers, and the industry as a whole to focus on the support of HIE infrastructure while supporting innovation in interoperable health IT development.

Comment: Many commenters expressed opposition to the objective noting a lack of participation by EPs to whom the referrals are made. A large number of commenters believe that they should not be penalized for other EPs inability to receive electronic delivery, something over which they state they have no control. In addition, some primary care doctors believe they are unfairly being held responsible for communicating with specialists who can claim an exclusion for referring less than 100 times. Many commenters requested that we reduce the threshold or change the measure to a yes/no attestation due to the lack of control over other EPs and eligible hospitals/CAHs without receiving capabilities. Many recommendations about the denominator varied, with some suggesting that the denominator referrals should exclude providers who are not EPs, eligible hospitals, or CAHs under the EHR Incentive Programs or should exclude patients who do not choose a specific provider for their recommended referral service. Commenters also requested various exclusions, including exclusions for transitions to pediatric providers, referrals to therapists, and for those in areas where there are not enough EPs

participating in Stage 2. Commenters requested clarifications on the measure regarding what constitutes “transfer of care” and what defines electronic transmissions.

Response: We appreciate the commenters’ concern about a lack of participation by EPs to whom the referrals are made and note that this is one reason behind the relatively low 10 percent threshold for this measure. We also note that in the proposed rule, we expressed a concern that a key factor influencing successful HIE is the active participation of a large number of providers in the process. We note that those providers who did participate in electronic exchange through Stage 2 in 2014 performed reasonably well on the measure, but through letters and public comment expressed a need for wider participation among providers to ensure a significant number of trading partners are available for electronic exchange. This is a driving influence behind our continued support of this measure and the move to require all providers to participate in this objective and measure beginning in 2016. The definition of a transition of care for this objective was finalized in the Stage 2 final rule where we outline the denominators for the various objectives and measures (77 FR 53984). We subsequently further defined (80 FR 16759) a transition of care for electronic exchange as one where the referring provider is under a different billing identity within the Medicare and Medicaid EHR Incentive Programs than the receiving provider and where the providers do not share access to the EHR. In cases where the providers do share access to the EHR, a transition or referral may still count toward the measure if the referring providers creates the summary of care document using CEHRT and sends the summary of care document electronically. If a provider chooses to include such transitions to providers where access to the EHR is shared, they must do so universally for all patient and all transitions or referrals.

Comment: Some commenters requested an extension of the alternate exclusion for Stage 1 providers into 2016 rather than only making this allowance for 2015.

Response: We do not believe that extending the alternate exclusion into 2016 serves the goals of the program to promote interoperability, an expanded HIT infrastructure, and the use of HIT to support care coordination. As noted previously, one of the biggest concerns expressed by providers seeking to engage in HIE is the need to increase overall participation to ensure an adequate pool of trading partners exists

within the industry. We believe that requiring all participating providers to exchange health information electronically when transitioning or referring a patient to a new setting of care, but maintaining the reasonably low threshold at 10 percent, represents a reasonable balance between promoting participation and setting an achievable goal for providers.

We acknowledge that in some cases we have decided to extend the alternate exclusion for 2015 into 2016 where a provider may not have the appropriate CEHRT functions in place for a measure. However, we have limited those instances to those cases where rushed implementation of the function could present a risk to patient safety. We do not believe this objective and measure pose such a risk, and further maintain our assertion from the Stage 3 proposed rule (80 FR 16739) that overall success on in health information exchange is enhanced by increased participation.

Comment: Many commenters supported the modified objective and the flexibility proposed around the pathways acceptable for transmitting Summary of Care records. Some commenters noted this change will facilitate queried exchange and encourage providers to push information to an HIE. Another commenter believes that this update will enhance the growth and utilization of the electronic exchange of information while upholding the same security standards as DIRECT or NwHIN.

Some commenters requested that we initiate the mandatory reporting of direct address directories to a central repository so that established standards will help providers meet future requirements in Stage 3.

Response: The intent behind the expansion of the potential transport mechanism proposed is to drive interoperability across care settings and encourage further innovation in electronic health information exchange and care coordination. We agree that the retention of the document standards for health information exchange will help to support interoperability, while allowing providers a wider range of options for the electronic transport mechanism. This will also mitigate difficulties for providers whose most common referrals may be to other caregivers who are not using a Direct transport mechanism. We note that CEHRT is required to be able to receive a C-CDA, but that the potential to use a wider range of transport mechanisms will allow for greater diversity of information exchange.

While we encourage the use of query-based exchange for many use cases, we note that to count in the numerator the sending provider must reasonable certainty of receipt of the summary of care document. This means that a “push” to an HIE which might be queried by the recipient is insufficient. Instead, the referring provider must confirmation that a query was made to count the action toward the measure. We further specify that the exchange must comply with the privacy and security protocols for ePHI under HIPAA.

We thank the commenters for the suggestion around the concept of an information exchange address repository. We agree that a potential model which might allow for easier access to health information exchange contact information could be a positive step toward supporting interoperability and an improved care continuum. We refer readers to section II.D.3 of this final rule with comment period for further discussion of the collection of direct addresses or health information exchange information for potential inclusion in a nationwide healthcare provider directory. After consideration of public comments received, we are finalizing this objective, measure, exclusion, and alternate exclusion as proposed for EPs, eligible hospitals, and CAHs as follows:

Objective 5: Health Information Exchange

Objective: The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

Measure: The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care must—(1) Use CEHRT to create a summary of care record; and (2) electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.

Threshold: The percentage must be more than 10 percent in order for an EP,

eligible hospital or CAH to meet this measure.

Exclusion: Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period.

Alternate Exclusion:

Alternate Exclusion: Provider may claim an exclusion for the Stage 2 measure that requires the electronic transmission of a summary of care document if for an EHR reporting period in 2015, they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

We are adopting Objective 5: Health Information Exchange at § 495.22(e)(5)(i) for EPs and § 495.22(e)(5)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 6: Patient-Specific Education

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20362), we proposed to retain the Stage 2 objective and measure for Patient-Specific Education for meaningful use for 2015 through 2017.

Proposed Objective: Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.

In the Stage 2 proposed rule (77 FR 54011), we explained that providing clinically relevant education resources to patients is a priority for the meaningful use of CEHRT. While CEHRT must be used to identify patient-specific education resources, these resources or materials do not have to be maintained within or generated by the CEHRT. We are aware that there are many electronic resources available for patient education materials, such as through the National Library of Medicine's MedlinePlus (<http://www.nlm.nih.gov/medlineplus>), that can be queried via CEHRT (that is, specific patient characteristics are linked to specific consumer health content). The EP or hospital should use CEHRT in a manner in which the technology suggests patient-specific educational resources based on the information created or maintained in the CEHRT. CEHRT is certified to use the patient's problem list, medication list, or laboratory test results to identify

the patient-specific educational resources. The EP or eligible hospital may use these elements or additional elements within CEHRT to identify educational resources specific to patients' needs. The EP or hospital can then provide these educational resources to patients in a useful format for the patient (such as electronic copy, printed copy, electronic link to source materials, through a patient portal or PHR).

Proposed EP Measure: Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.

We proposed to retain the exclusion for EPs who have no office visits in order to accommodate such EPs.

The resources would have to be those identified by CEHRT. If resources are not identified by CEHRT and provided to the patient, then it would not be counted in the numerator. We do not intend through this requirement to limit the education resources provided to patients to only those identified by CEHRT. The education resources would need to be provided prior to the calculation and subsequent attestation to meaningful use.

To calculate the percentage for EPs, CMS, and ONC have worked together to define the following for this objective:

Denominator: Number of unique patients with office visits seen by the EP during the EHR reporting period.

Numerator: Number of patients in the denominator who were provided patient-specific education resources identified by the CEHRT.

Threshold: The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources identified by CEHRT.

To calculate the percentage for hospitals, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of unique patients admitted to the eligible hospital or CAH inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.

Numerator: Number of patients in the denominator who are subsequently provided patient-specific education resources identified by CEHRT.

Threshold: The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

While the Patient-Specific Education objective is designated as an optional menu objective in Stage 1, the same objective is a mandatory core objective in Stage 2. We expect that not all Stage 1 scheduled providers were planning to choose this menu objective when attesting in an EHR reporting period in 2015. Therefore, we proposed that any provider scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 who was not intending to attest to the Stage 1 Patient-Specific Education menu objective, may claim an exclusion to the measure. We note that for an EHR reporting period beginning in 2016, all providers must attest to the objective and measure and meet the Stage 2 specifications and threshold in order to successfully demonstrate meaningful use.

Proposed Alternate Exclusion: Providers may claim an exclusion for the measure of the Stage 2 Patient-Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Patient Specific Education menu objective.

We proposed no alternate specifications for this objective.

Comment: The vast majority of commenters expressed support for the inclusion of the Patient-Specific Education objective in the EHR Incentive Programs for 2015 through 2017 proposed rule. They recognized the importance of supplying patients with materials about their conditions and summaries about their visits.

Response: We thank the commenters for their support of this objective.

Comment: Those who opposed the objective believe that the inclusion of the objective in the EHR Incentive Programs for 2015 through 2017 proposed rule increased administrative burden on providers. Some commenters opposed to the objective believe that physicians should have flexibility regarding the sources and types of materials they can provide to their patients, rather than being limited to those identified by CEHRT.

Response: We appreciate the insight from providers and note that the intent of the objective is to promote wider availability of patient-specific education leveraging the function of CEHRT, as noted in the similar, electronic-only

Stage 3 proposed measure. We note that this should in no way limit the provider's selection of patient-specific education materials or provision of paper-based education materials for patients if the provider deems such an action beneficial and of use to the patient. We are simply not requiring providers to count and report any such provision that falls outside the definition for the EHR Incentive Programs for 2015 through 2017 as described in this objective and measure.

Comment: Multiple commenters requested clarification of the timeframe in which the information should be shared with the patient. Commenters specifically requested additional clarity on FAQ 8231⁷ released by CMS, stating the actions taken would need to fall within the reporting year, even if they fall outside of the reporting period. For the patient education measure of this objective, some commenters believe requiring the action to occur during the reporting period promotes wasted resources and functions from the provider. Specialty providers who are providing long-term care for a patient would need to send out patient education for what would amount to the same problem each year. This education could have been provided in a previous year to the patient, and the FAQ is stating the patient be provided the education again in order to count for the numerator in the current reporting year. Commenters further noted that many specialist EPs provide education at the beginning of an engagement with a patient appropriate to their condition with the intent that it be applicable to the entire duration of the treatment of the patient's condition. Commenters expressed concern that the policy would require the provider to either provide repetitive education or identify additional educational opportunities in order to count the action in the numerator. The commenters state that allowing for any prior action to count would reduce the unnecessary burden placed on physicians, and the waste of resources to provide the patient with repetitive information.

Response: As discussed in section II.B.1.b.(4), some measures in the Stage 2 final rule did not include a specification on the timing when an action must occur for inclusion in the numerator. The Stage 2 patient-specific education objective did not contain language stating that the provision of patient-specific education must occur within the office visit or during the

hospital stay. For EPs the measure states only that the patient had an office visit during the EHR reporting period and was provided patient-specific education. This could refer to materials provided during an office visit or at another point in time.

However, we disagree with the recommendation to allow any action to count in perpetuity. We note that this measure refers to a single action for each unique patient seen during the EHR reporting period. This means that if a provider meets the minimum action, even for those patients who have multiple office visits within an EHR reporting period, the provider would be providing educational information a single time each year for only just over 10 percent of their patients. We strongly disagree that this represents an unreasonable burden or that this action should not be required to continue on an annual basis. We disagree with the commenter's suggestion that patient specific education is not useful or relevant for a patient for each year in which they receive medical care. We further disagree with the examples provided for specialists or other providers providing long-term care or working with a patient to manage a chronic disease that a single provision of patient specific education should be counted for the numerator in perpetuity. Research shows that continued patient engagement and education positively impacts patient outcomes, especially for patients with a chronic disease and patients who may experience health disparities.⁸ In addition, as a patient ages, or as their health condition changes, their needs for education about their care may also change.

Therefore, as indicated in FAQ 8231, we believe that while the patient-specific education resources may be provided outside of the EHR reporting period, this action must occur no earlier than the start of the same year as the EHR reporting period if the EHR reporting period is less than one full calendar year and no later than the date of attestation. For the eligible hospital and CAH measure, the numerator includes the qualifier "subsequently" which indicates the patient-specific education resources must be provided after the patient's admission to the

hospital, and consistent with FAQ 8231, no later than the date of attestation. As noted in section II.B.1.b.(4)(b), some EHRs may have previously been designed and certified to calculate this measure based on a prior assumption, and for that reason we will not require this method of calculation until the EHR reporting period in 2017 in order to allow sufficient time for the calculation to be updated in systems.

Comment: Other commenters were concerned that the exclusion for providers who were scheduled for Stage 1 but "did not intend to select the Stage 1 Patient Education menu objective" is vague and will lead to audit problems.

Response: We refer readers to the discussion of intent in section II.B.1.b.(4).(b)(iii) of this final rule with comment period where we acknowledge that it may be difficult for a provider to document intent and will not require such documentation.

Comment: Multiple commenters recommended that we add the Patient-Specific Education objective to the list of topped-out measures. Another group of commenters recommended that we provide an alternate measure for eligible hospitals/CAHs/EPs that were scheduled to be in Stage 1 in 2015 and desired to select patient education as a menu objective utilizing the current Stage 1 measure definition. Others recommended we require that providers have multi-lingual and low-literacy patient portals.

Response: We respectfully disagree that the measure is topped out and believe there is value in continued measurement especially in light of the inclusion of the similar electronic measure within Stage 3. We also disagree with the recommendation to include an alternate specification for the measure in addition to the alternate exclusion. While the policy would allow some providers to attest, it adds an additional level of complexity and makes no accommodation for those providers in 2015 who have not been engaged in the measure at all, as they did not intend to attest to that menu selection. Finally, we appreciate the recommendation on the inclusion of multi-lingual and low-literacy patient portals to provide and support patient education for a wider range of patients. We note that it is a priority of CMS and ONC to continue to foster interoperability between assistive technologies, portals such as those recommended by the commenters, applications leveraging multi-media supports, and other accessible tools and CEHRT. Unfortunately, while we strongly encourage adoption of these resources and support the development

⁷ FAQ #8231: CMS Frequently Asked Questions: EHR Incentive Programs <https://questions.cms.gov/faq.php?faqId=8231>.

⁸ "Patient Education and Empowerment Can Improve Health Outcomes for Diabetes" NY Presbyterian DSME study August 2014: <http://www.nyp.org/news/hospital/2014-education-diabetes.html>.

Keolling, Todd M., MD; Monica L. Johnson, RN; Robert J. Cody, MD; Keith D. Aaronson, MD, MS: "Discharge Education Improves Clinical Outcomes in Patients with Chronic Heart Failure" Heart Failure: AHA Journals: <http://circ.ahajournals.org/content/111/2/179.full>.

of standards and testing, we believe the requirement of these tools for all providers in the Medicare and Medicaid EHR Incentive Programs is premature based on the current availability of such interoperable resources in the EHR marketplace.

Comment: Some commenters requested clarification if the transitive effect described in FAQ 7735 and FAQ 9686 applies for the patient-specific education objective as well. These commenters note that if patient-specific education is provided via a patient portal, it is very difficult to measure as attributable to a specific provider within a group practice or even across settings if providers are sharing an EHR.

Response: FAQ7735 and FAQ 9686 refer to the Patient Electronic Access Objective measures 2 and the Secure Electronic Messaging Objective respectively,⁹ and allow for a single action by a patient to count in the numerator for multiple providers under certain circumstances if each of the providers has the patient in their denominator for that EHR reporting period. In each case, this policy is intended to facilitate calculation in circumstances where accurate calculation and attribution of the action to a single provider may be impossible. This is not inherently the case with the patient-specific education objective which is why this objective is not included in either FAQ. The Stage 2 Patient-specific Education Objective (80 FR 20362) does not limit the measure to education provided via a patient portal and therefore a universal policy allowing the “transitive effect” would not be appropriate. For example, if a provider gives a patient a paper-based educational resource during their office visit, that instance is only attributable to that provider and should not be counted in the numerator for other providers within the group practice. However, if the resource is provided electronically and such attribution is impossible, it may be counted in the numerator for any provider within the group sharing the CEHRT who has contributed information to the patient’s record, if that provider also has the patient in their denominator for the EHR reporting period. We recognize that this may result in a process of manual calculation if both electronic and paper-based resources are used. While we are seeking to avoid manual calculation and paper-based actions, we must also balance avoiding unintended negative

consequences which may result from changing the specifications for this measure for providers who are currently using paper-based methods. For information on the fully electronic Patient-specific Education measure included in the Stage 3 proposed rule, we direct readers to section II.B.2.b.vi of this final rule with comment period.

After consideration of public comments received, we are finalizing the objective, measures, exclusions, and alternate exclusion as proposed for EPs, eligible hospitals and CAHs.

The final objective is as follows:

Objective 6: Patient-Specific Education

Objective: Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.

EP Measure: Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.

- *Denominator:* Number of unique patients with office visits seen by the EP during the EHR reporting period.
- *Numerator:* Number of patients in the denominator who were provided patient-specific education resources identified by the CEHRT.

- *Threshold:* The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

- *Exclusion:* Any EP who has no office visits during the EHR reporting period.

Eligible Hospital/CAH Measure: More than 10 percent of all unique patients admitted to the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period are provided patient-specific education resources identified by CEHRT.

- *Denominator:* Number of unique patients admitted to the eligible hospital or CAH inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.

- *Numerator:* Number of patients in the denominator who are subsequently provided patient-specific education resources identified by CEHRT.

- *Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

Alternate Exclusion:

Alternate Exclusion: Providers may claim an exclusion for the measure of the Stage 2 Patient-Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend

to select the Stage 1 Patient Specific Education menu objective.

We are adopting Objective 6: Patient-Specific Education at § 495.22(e)(6)(i) for EPs and § 495.22(e)(6)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 7: Medication Reconciliation

In the EHR Incentive Programs for 2015 through 2017 proposed rule (80 FR 20363), we proposed to retain the Stage 2 objective and measure for Medication Reconciliation for meaningful use in 2015 through 2017. Medication reconciliation allows providers to confirm that the information they have on the patient’s medication is accurate. This not only assists the provider in his or her direct patient care, it also improves the accuracy of information they provide to others through health information exchange.

Proposed Objective: The EP, eligible hospital, 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.

In the Stage 2 proposed rule at 77 FR 54012 through 54013, we noted that when conducting medication reconciliation during a transition of care, the EP, eligible hospital, or CAH that receives the patient into their care should conduct the medication reconciliation. We reiterated that the measure of this objective does not dictate what information must be included in medication reconciliation, as information included in the process is appropriately determined by the provider and patient. We defined medication reconciliation as the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency, and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider. In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20363), we proposed to maintain these definitions without modification.

Proposed Measure: The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the

⁹ CMS.gov Frequently Asked Questions: EHR Incentive Programs FAQ 7735: <https://questions.cms.gov/faq.php?id=5005&faqId=7735> and FAQ 9686: <https://questions.cms.gov/faq.php?id=5005&faqId=9686>.

patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of transitions of care during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the receiving party of the transition.

Numerator: The number of transitions of care in the denominator where medication reconciliation was performed.

Threshold: The resulting percentage must be more than 50 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who was not the recipient of any transitions of care during the EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed that any provider scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 who was not intending to attest to the Stage 1 Medication Reconciliation menu objective, may claim an exclusion to the measure.

Proposed Alternate Exclusion: Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.

We proposed no alternate specifications for this objective.

Comment: One commenter requested clarification of whether CMS intends to limit the denominator of this proposed measure to transitions of care, or if certain referrals would also continue to be included as was the case prior to this rulemaking. Another commenter stated that they believe their CEHRT incorrectly includes encounters in the denominator where no actual transition of care is occurring or where the encounter is not a face-to-face encounter with the patient.

Many commenters provided recommendations for additional exclusions for the objective including exclusions for providers who do not have office visits; and providers who have fewer than 10 or 100 transitions of care rather than limiting the exclusion to providers who not the recipient of any transition or referral. Another commenter believes that medication

reconciliation is out of scope for his practice while others requested excluding referrals for reading certain tests or imaging services. Commenters also requested that we revise the measure to allow an exclusion for providers with fewer than 100 transitions or referral received electronically or to limit the denominator to only those transitions or referrals where an electronic summary of care document was received.

Finally, one commenter stated a belief that the requirements for medication reconciliation objective depend upon the interoperability of EHR systems and may pose a significant burden to providers.

Response: We reiterate that in the EHR Incentive Program for 2015 through 2017 (80 FR 20363), we proposed to maintain the denominators finalized through rulemaking in the Stage 2 final rule (77 FR 54012 through 54013 and 53982 through 53984), including the current definition of a transition of care for inclusion in the denominator of this measure. We note that the denominator includes when the provider is the recipient of the transition or referral, first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving provider (77 FR 53984).

In addition, for those EPs who note that they have no office visits, or face-to-face encounters, and therefore should not have to include patient encounters for these services (such as only reading an EKG); we refer readers to the description in the Stage 2 final rule (77 FR 53982) which notes that a provider may choose to include these encounters in the denominator or to exclude them. However, if the provider chooses to include or exclude these encounters they must apply the policy universally across all such encounters and across all applicable measures. A provider should consider how the policy will affect their ability to meet all applicable measures, and then work with their EHR vendor to ensure that the calculation of denominators and numerators matches the provider's decision.

In terms of additional or expanded exclusions or concerns over scope of practice, we note that we did not propose any such changes and disagree that any such changes are necessary or beneficial. We believe medication reconciliation is an important part of maintaining a patient's record, that it is integral to patient safety, and that maintaining an accurate list of medications may be relevant to any provider's plan of care for a patient.

In addition, robust health information exchange is of great assistance to medication reconciliation, but an electronic summary of care document is not required for medication reconciliation. Nor is electronic HIE the only way EHRs can assist with medication reconciliation. Medication reconciliation may take many forms, from automated inclusion of ePHI to review of paper records, to discussion with the patient upon intake or during consultation with the provider. Going back to Stage 1 we have noted that medication reconciliation may become more automated as technology progresses, but may never reach a point of full automation as these other methods continue to offer value—especially conversation with the patient which may remain an important part of that process (75 FR 44362).

Furthermore, while the measure does involve health information exchange, we see no value in limiting the medication reconciliation measure to only those patients for whom a record is received electronically. We believe that it is appropriate and important to conduct medication reconciliation for each patient regardless of the method that reconciliation may require. Therefore, while we believe that medication reconciliation will become easier as health information exchange capability increases and that robust health information exchange supports medication reconciliation, it is not a prerequisite to performing medication reconciliation. Further, we believe the continued inclusion of a broad requirement for medication reconciliation will encourage developers and providers to continue to focus on how HIT can be designed and leveraged to better support provider medication reconciliation workflows through innovative new tools and resources.

Comment: A commenter recommended that we require medication reconciliation when a provider receives a Summary of Care that is not a duplicate document and only reconcile if there are changes to the medication list. Another commenter requested that automated results should only be counted if there are medications in the queried document so it is possible to “compare the medical record to an external list of medications obtained from a patient, hospital, or other provider.”

Response: We note that we discuss the denominator for a transition of care in section II.B.1.b.(4)(f) of this final rule with comment period and that in the EHR Incentive Programs in 2015 through 2017 proposed rule at (80 FR

20363) we proposed to maintain the definition for this objective from the Stage 2 final rule when the EP is the recipient of the transition or referral, first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP (77 FR 53984). We note that the reconciliation occurs with the transition or referral, not with the receipt of the summary of care document. Therefore, if a provider receives duplicate summaries for a single referral such an action must only be counted once. In addition, the action of reviewing the medication list to determine if there are changes or confirm that there are no changes would meet the requirements of the objective to count as an action in the numerator.

Comment: Commenters requested that CMS define what a “new” patient is for the purposes of the definition of a transition or referral. For example, one commenter noted that in their billing practices they define a patient as “new” if they have not been seen in 2 years. The commenter noted that using this definition in the denominator would include a greater number of relevant patient encounters than our current definition which uses patients who were never before seen by the provider. The commenter suggested this definition would ensure that these patients records were also updated which would be a significant benefit.

Response: In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20363) as in the Stage 2 final rule (77 FR 54013), we consider a patient to be a new patient if he or she has never before been seen by the provider. We agree that the commenter’s definition of “new patient” may capture a wider range of patients for whom medication reconciliation would be relevant and beneficial. While we will not change the denominator for this existing objective, a provider may use an expanded definition which includes a greater number of patients for whom the action may be relevant within their practice. We intend that our description of a new patient is a baseline that a provider must meet; however, if that requirement is met the provider may include further actions or addition encounters relevant to their practice and patient population, so long as the approach is applied universally across all such encounters, all settings and for the duration of the EHR reporting period.

Comment: A commenter requested clarification of whether the denominator of medication reconciliation includes first encounters with all new patients (in other words, “encounters in which

the provider has never before encountered the patient” as specified in the Stage 3 proposal) or only those new patients that are accompanied by a summary of care record.

Response: For providers who are on the receiving end of a transition of care or referral, the denominator includes first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving provider.

Comment: A commenter requested clarification of whether CMS intends to limit the denominator of this proposed measure to transitions of care, or if certain referrals would also continue to be included as was the case prior to this rulemaking.

Response: For the purposes of this measure, we continue to maintain the definition of a transition of care as the movement of a patient from one setting of care (for example, a hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. Referrals are cases where one provider refers a patient to another, but the referring provider maintains his or her care of the patient as well. Thus, the denominator includes both transitions of care and referrals in which the provider was the transferring or referring provider.

Comment: The proposal to allow exclusion for this measure if a provider was scheduled for Stage 1 but “did not intend to select the Stage 1 Medication Reconciliation menu objective” is vague and will lead to audit problems. It should just be clearly stated that this is exclusion for Stage 1 EPs.

Response: As explained in section II.B.1.b.(4)(b)(iii) of this final rule with comment period where we acknowledge that it may be difficult for a provider to document intent and will not require such documentation.

Comment: While the commenter agrees that medication reconciliation is a critical patient care requirement when patients move from one setting of care to another, they encourage us to specify that transitions from physicians who furnish services in POS 22 code should not be considered “transitions of care” for purposes of this objective and measure.

Response: We note that we make no distinction between settings nor do we reference any POS code for the party transitioning the patient. We consider a transition as the movement of a patient from one care setting to another. We reference POS in this objective only with regard to the inclusion of patients admitted to either the Inpatient or Emergency Department (POS 21 and 23)

in the denominator. We see no reason that patients referred from a provider billing under a POS 22 should not be included in the definition of a transition or referral.

After considerations of public comments received, we are finalizing as proposed the objective, measure, exclusion and alternate exclusions for EPs, eligible hospitals, and CAHs as follows:

Objective 7: Medication Reconciliation

Objective: The EP, eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant performs medication reconciliation.

Measure: The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23).

- *Denominator:* Number of transitions of care during the EHR reporting period for which the EP or eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) was the receiving party of the transition.

- *Numerator:* The number of transitions of care in the denominator where medication reconciliation was performed.

- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP, eligible hospital or CAH to meet this measure.

- *Exclusion:* Any EP who was not the recipient of any transitions of care during the EHR reporting period.

Alternate Exclusion:

Alternate Exclusion: Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.

We are adopting Objective 7: Medication Reconciliation at § 495.22(e)(7)(i) for EPs and § 495.22(e)(7)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 8: Patient Electronic Access

We proposed to retain the Stage 2 objective for Patient Electronic Access for meaningful use in 2015 through 2017. We proposed to retain the first measure of the Stage 2 objective without modification. We proposed to retain the second measure for the Stage 2 objective with modification to the measure threshold.

Proposed EP Objective: Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

Proposed Eligible Hospital/CAH Objective: Provide patients the ability to view online, download, and transmit their health information within 36 hours of hospital discharge.

In the Stage 2 proposed rule, we stated that the goal of this objective was to allow patients easy access to their health information as soon as possible, so that they can make informed decisions regarding their care or share their most recent clinical information with other health care providers and personal caregivers as they see fit.

The ability to have this information online means it is always retrievable by the patient, while the download function ensures that the patient can take the information with them when secure internet access is not available. The patient must be able to access this information on demand, such as through a patient portal or PHR. We note that while a covered entity may be able to fully satisfy a patient's request for information through VDT, the measure does not replace the covered entity's responsibilities to meet the broader requirements under HIPAA to provide an individual, upon request, with access to PHI in a designated record set. Providers should also be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access there may be patients who cannot access their EHRs electronically because of their disability, or who require assistive technology to do so. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws, including the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, or Section 1577 of the Affordable Care Act, must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations. For a useful reference of how to meet these obligations, we

suggest covered providers reference the Department of Justice's Effective Communications guidance at <http://www.ada.gov/effective-comm.htm>.

Proposed EP Measures:

- *EP Measure 1:* More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

- *EP Measure 2:* At least one patient seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits his or her health information to a third party.

In order to meet this objective, the following information must be made available to patients electronically within 4 business days of the information being made available to the EP:

- ++ Patient name.
- ++ Provider's name and office contact information.
- ++ Current and past problem list.
- ++ Procedures.
- ++ Laboratory test results.
- ++ Current medication list and medication history.
- ++ Current medication allergy list and medication allergy history.
- ++ Vital signs (height, weight, blood pressure, BMI, growth charts).
- ++ Smoking status.
- ++ Demographic information (preferred language, sex, race, ethnicity, date of birth).
- ++ Care plan field(s), including goals and instructions.
- ++ Any known care team members including the primary care provider (PCP) of record.

To calculate the percentage of the first measure for providing patient with timely online access to health information, CMS and ONC have worked together to define the following for this objective:

- *Proposed EP Measure 1:* More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

Denominator: Number of unique patients seen by the EP during the EHR reporting period.

Numerator: The number of patients in the denominator who have timely (within 4 business days after the information is available to the EP)

online access to their health information.

Threshold: The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

- *Proposed EP Measure 2:* At least one patient seen by the EP during the EHR reporting period (or his or her authorized representatives) views, downloads, or transmits his or her health information to a third party.

- *Proposed Exclusions:* Any EP who—

(a) Neither orders nor creates any of the information listed for inclusion as part of the measures; or

(b) Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Proposed Eligible Hospital/CAH Measures:

- *Eligible Hospital/CAH Measure 1:* More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

- *Eligible Hospital/CAH Measure 2:* At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads or transmits to a third party his or her information during the EHR reporting period.

The following information must be available to satisfy the objective and measure:

- ++ Patient name.
- ++ Admit and discharge date and location.
- ++ Reason for hospitalization.
- ++ Care team including the attending of record as well as other providers of care.
- ++ Procedures performed during admission.
- ++ Current and past problem list.
- ++ Vital signs at discharge.
- ++ Laboratory test results (available at time of discharge).
- ++ Summary of care record for transitions of care or referrals to another provider.
- ++ Care plan field(s), including goals and instructions.
- ++ Discharge instructions for patient.
- ++ Demographics maintained by hospital (sex, race, ethnicity, date of birth, preferred language).
- ++ Smoking status.

To calculate the percentage of the first measure for providing patients timely

access to discharge information, CMS and ONC have worked together to define the following for this objective:

- *Proposed Eligible Hospital/CAH Measure 1:* More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

Denominator: Number of unique patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator whose information is available online within 36 hours of discharge.

Threshold: The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

- *Proposed Eligible Hospital/CAH Measure 2:* At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads or transmits to a third party his or her information during the EHR reporting period.

- *Proposed Exclusion:* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed that providers scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may additionally claim an exclusion for the second measure of the Stage 2 Patient Electronic Access objective because there is not an equivalent Stage 1 measure defined at 42 CFR 495.6.

Proposed Alternate Exclusion Measure 2: Providers may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

We proposed no alternate specifications for this objective.

Comment: Many commenters appreciate the proposed modifications to the objective's measures that rely on patient's actions. Many respondents believe the flexibility provided in the modifications will provide more time for both providers and patients to

become more comfortable accessing and using patient portals, and will not penalize providers for failing to meet thresholds based on patient actions they cannot control.

Response: We thank the commenters for their feedback concerning this proposed change in the EHR Incentive Programs in 2015 through 2017.

Comment: A number of commenters opposed our proposal to modify the second measure requiring that patients taking action to view, download, or transmit their health information. These commenters stated concern that the change will have a negative effect on patients access to their health record because it will allow providers to stop investing in the workflows, training, and patient education needed to support patient access.

Other commenters urged CMS to "preserve the existing thresholds for patient online access and secure, messaging" stating that requiring that only one patient has access is not meaningful enough. These commenters included statements advocating for patients to have the ability to access their EHR and that we should not reduce the threshold to let providers off the hook.

Response: We appreciate the commenters' advocacy for patients and agree that patient electronic access to health information is essential to improving the quality of care. However, we disagree that reducing the patient action measure will negatively impact the workflows, training, and patient education for patient access because the patient access measure is still fully in place: That is, measure 1 which requires providers to ensure that more than 50 percent of patients are provided access to their health information. This measure requires that providers ensure that patients have all the information they need to access their record, even for patients who may choose to opt out, so a provider cannot stop doing the workflows, training, and patient education for patient access and still meet the requirements of meaningful use for measure one of this objective.

For the commenters who state that one patient having access is not meaningful enough, we believe these commenters may have misunderstood which measure we proposed to modify. As noted, we proposed no changes to the first measure under the Patient Electronic Access objective which is required for all providers in Stage 1 and Stage 2, in Medicare and Medicaid, and for both EPs, eligible hospitals, and CAHs. For this measure, each provider must demonstrate that more than 50 percent of their unique patients during

the EHR reporting period have access to view, download, and transmit their health information. In the proposed rule, we proposed only to modify the second measure (which measures the patient's action, not the provider) from a threshold of 5 percent to at least one patient.

Comment: While some commenters supported EP Measure 1 as proposed, many more were concerned with patients' general ability to access their health information. A portion of respondents in disagreement with Measure 1 were concerned the 50 percent threshold will be unattainable because their patient population is elderly, ill, low-income, and/or located in remote, rural areas. These patients do not have access to computers, Internet and/or email and are concerned with having their health information online. Several others believe Measure 1 is unnecessary, as patients must use the access provided in order for an EP, eligible hospital or CAH to meet Measure 2 of this objective. A number of commenters also disagreed with the requirement for the provision of new information within 36 hours for eligible hospitals and CAHs (four business days for EPs) stating that it was either too long a time for patients to wait or too short a time for providers to respond.

Response: We have proposed no changes to the first measure and reiterate our intent to maintain the first measure as previously finalized in the Stage 2 final rule. We note that providing access to patients to view, download, and transmit their information is a top priority for patient engagement, patient-centered care, and care coordination. We note that in the EHR Incentive Programs, the specifications for the measure allow the provision of access to take many forms and do not require a provider to obtain an email address from the patient. We understand that many CEHRT products may be designed in that fashion, but it is not by the program.

If a provider's CEHRT does require a patient email address, but the patient does not have or refuses to provide an email address or elects to "opt out" of participation, that is not prohibited by the EHR Incentive Program requirements nor does it allow the provider to exclude that patient from the denominator. Instead, the provider may still meet the measure by providing that patient all of the necessary information required for the patient to subsequently access their information, obtain access through a patient-authorized representative, or otherwise opt-back-in without further follow up action required by the provider. We note

that we have proposed no changes to the timeframe for provision of new information and maintain that 36 hours (for eligible hospitals and CAHs) and 4 business days (for EPs) is a reasonable time limit because it allows for immediate access (if feasible) and a reasonable amount of time for providers to review any information necessary before it is made available to the patient.

Comment: A commenter noted that the patient access measure 1 needs clarification as to when it must occur in relation to the EHR reporting period. The commenter further stated that once a patient has been provided access there is no need to provide additional access unless the patient originally opted out of receiving electronic access. The commenter further noted that active, ongoing access that preceded the EHR reporting period should always count in the numerator for a patient seen during the EHR reporting period. The commenter also states that when a patient opts out of electronic access, as long as the patient was properly educated on the portal and how to gain access, there should be no need to count access again.

Further commenters referenced EHR Incentive Programs FAQ 8231¹⁰ and recommended that we clarify measure one and measure 2, and suggested that all measure with a denominator referencing unique patient should allow a provider to count actions from any time period before the reporting period or reporting year to count in the numerator.

Response: We believe the confusion on this issue for the first measure may relate to the ways in which different EHRs are set up to initiate access for a patient the first time. The measure does not address the enrollment process or how the initiation process to “turn on” access for a patient within an EHR system should function. The measure is addressing the health information itself. To count in the numerator, this health information needs to be made available to each patient for view, download, and transmit within 4 business days of its availability to the provider for each and every time that information is generated whether the patient has been “enrolled” for three months or for three years. We note that a patient needs to be seen by the EP during the EHR reporting period or be discharged from the hospital inpatient or emergency department during the EHR reporting period in order to be included in the denominator.

For example, if a provider’s CEHRT uses an enrollment process to issue a user ID to the patient, a provider does not need to create a new user ID for a patient each time the patient has an office visit. That initial enrollment can occur any time as it is not governed by the measure. What the measure addresses is the health information that results from care (e.g. from an office visit or a hospital admission). The measure timeline for making any health information available resets to 36 hours for an eligible hospital or CAH and 4 business days for an EP each time new information is available to which the patient should be provided access. Therefore, although a provider does not need to enroll a unique patient a second time if the patient has a second office visit during the EHR reporting period, the provider must continue to update the information accessible to the patient each time new information is available. In addition, if the provider fails to provide access to a patient upon an initial visit during the EHR reporting period, but provides access on a subsequent visit, the patient cannot be counted in the numerator because the patient did not have timely online access to health information related to the first visit. Similarly, the patient cannot be included in the numerator if access is provided on the first visit, but the provider fails to update the information within the time period required after the second visit. In short, a patient who has multiple encounters during the EHR reporting period, or even in subsequent EHR reporting periods in future years, needs to have access to the information related to their care for each encounter where they are seen by the EP or discharged from the eligible hospital or CAH’s inpatient or emergency department.

In relation to the suggestion that the second measure should be allowed to be calculated including any action in any time period before the EHR reporting period to count in the numerator, we strongly disagree. We do not believe a single instance of a patient accessing their record should be counted in perpetuity for the measure. The calculation may include actions taken before, during, or after the EHR reporting period if the period is less than one full year; however, consistent with FAQ 8231, these actions must be taken no earlier than the start of the same year as the EHR reporting period and no later than the date of attestation. We understand, as discussed in section II.B.1.b.(4), that some certified EHRs may not calculate the numerator in this fashion and therefore we will allow

providers to use an alternate calculation for an EHR reporting period in 2015 and 2016 if that calculation is a part of their CEHRT to allow sufficient time to upgrade the calculation prior to providers attesting to data for an EHR reporting period in 2017.

Comment: Those commenters in support of the changes to measure 2 of this objective supported our incorporation of stakeholder and participant feedback into the modifications of this measure. Supporting commenters agreed with the proposed patient engagement threshold reduction, stating that it is currently unattainable for their practice due to a patient population that is elderly, ill, low-income, and/or located in remote, rural areas. For these sites, commenters believe lowering the threshold will permit them flexibility in working with their vendors and developing new approaches to increase their patient engagement.

Response: We thank the commenters for their contribution. We believe that continued efforts to raise awareness and provide access through a wider range of electronic means (such as the inclusion of APIs in the Stage 3 measure) will help to expand the adoption of this technology over time.

Comment: The majority of commenters concerned about the modifications of Measure 2 believe lowering the patient engagement threshold is counter-productive for improving patient outcomes and moving the meaningful use program forward. Commenters worry the new threshold is much too low to incentivize providers to encourage patient access to the electronic health records that are central to the overarching goal of meaningful use.

Some commenters disagreed with the modifications to Measure 2 and are concerned with the large jump to meet the proposed Stage 3 meaningful use VDT requirement in 2018. Several commenters believe that the reduction of the patient engagement threshold will slow momentum of this measure leaving providers ill-prepared for the future of meaningful use. Many commenters believed that lowering the requirement to only one patient viewing, downloading, or transmitting their health information is counterproductive to improving patient outcomes nationally. Engaging patients by using technology is a critical path to move the healthcare system forward and demonstrate the core value of meaningful use. Several commenters recommended a phased approach for the threshold for the measure, increasing over time to the proposed

¹⁰FAQ 8231. www.cms.gov/ehrincentiveprograms CMS Frequently Asked Questions: EHR Incentive Programs (archived).

Stage 3 level. They recommended a phased approach that recognizes the challenges that some providers are encountering as they try to get their patient population more engaged with viewing, downloading or transmitting their information to a third party. They believe that a higher measure threshold will be easier to achieve as the technology becomes even more user-friendly and patients begin to see the value in becoming more involved in their own care and taking these actions. Overall, they believe a phased-in approach for the patient electronic access objective would be an appropriate and balanced step forward.

Response: We agree that providers have a role in promoting behavioral change among patients in regard to engaging with their health information and increasing health literacy and that provider influence may be a factor. However, as noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20357), statistical analysis of measure performance shows a wide variance, and further analysis in comparison to the first measure does not show a correlation between provider action and patient response.¹¹ Through our analysis we found that neither high nor low performance on the first measure nor an overall increase or decrease in the number of patients who have access to their data, had a strong or moderate correlation to performance on patient action either for high performers or low performers. This suggests that other external factors currently impact performance on the objective. This may include a lag in the adoption of technologies by patients, patient self-selection, or other unknown factors related to the IT environment and the patients themselves. We believe that continued efforts to raise awareness and provide access through a wider range of electronic means (such as the inclusion of APIs in the Stage 3 measure) will help to expand the adoption of this technology over time, and we maintain that providers should be supported in that effort rather than having additional burden added for factors outside their control.

We wish to reiterate that we understand the concerns voiced by providers regarding patient populations that are unable to engage in their health care information electronically due to various factors, which include income, age, technological capabilities, or comprehension. We agree with the phased approach recommended by the

commenters who noted that it provides additional time for the adoption of technology by patients, but also maintains the importance of the measure. We believe this approach will allow providers to set a progressive goal with incremental increases in performance through 2018. We believe this approach is in line with our policy to build from basic to advanced use and to increase measure thresholds over time and that it will also maintain the incentive for providers to focus on methods and approaches to increase patient engagement. Therefore, we are finalizing a change from our proposal for 2015 through 2017 to build toward the Stage 3 measure threshold required in 2018. We are setting the measure threshold at 1 patient for 2015 and 2016 and 5 percent in 2017 to work toward the increased threshold for Stage 3 in 2018 (see also section II.B.2.b.(vi) for the Stage 3 objective).

After consideration of public comment received, we are finalizing the objective and the alternate exclusion to Measure 2 as proposed for EPs, eligible hospitals and CAHs.

We are finalizing Measure 1 with modifications to improve the clarity of the measure language based on stakeholder feedback and Measure 2 with modifications to the thresholds and to specify the timing of the action for EPs to match the eligible hospital and CAH measure. We are maintaining our prior policy for the information that must be provided to the patient for the objective as proposed.

We are adopting the objective as follows:

Objective 8: Patient Electronic Access

EP Objective: Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

EP Measure 1: More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information.

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.

- *Numerator:* The number of patients in the denominator who have access to view online, download and transmit their health information within 4 business days after the information is available to the EP.

- *Threshold:* The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

EP Measure 2: For an EHR reporting period in 2015 and 2016, at least one patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.

- *Numerator:* The number of patients in the denominator (or patient-authorized representative) who view, download, or transmit to a third party their health information.

- *Threshold:* The numerator and denominator must be reported, and the numerator must be equal to or greater than 1.

- *Exclusions:* Any EP who—
 - Neither orders nor creates any of the information listed for inclusion as part of the measures; or
 - Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

For an EHR reporting period in 2017, more than 5 percent of unique patients seen by the EP during the EHR reporting period (or his or her authorized representatives) view, download or transmit to a third party their health information during the EHR reporting period.

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.

- *Numerator:* The number of patients in the denominator who view, download, or transmit to a third party their health information.

- *Threshold:* The resulting percentage must be greater than 5 percent.

- *Exclusions:* Any EP who—
 - Neither orders nor creates any of the information listed for inclusion as part of the measures; or

- Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Eligible Hospital/CAH Objective: Provide patients the ability to view online, download, and transmit their health information within 36 hours of hospital discharge.

Eligible Hospital/CAH Measure 1: More than 50 percent of all unique patients who are discharged from the

¹¹ EHR Incentive Programs Performance Data: Program Data and Reports: www.cms.gov/EHRIncentivePrograms.

inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH are provided timely access to view online, download and transmit to a third party their health information.

- *Denominator*: Number of unique patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator*: The number of patients in the denominator who have access to view, download, and transmit their health information within 36 hours after the information is available to the eligible hospital or CAH.

- *Threshold*: The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

Eligible Hospital/CAH Measure 2: For an EHR reporting period in 2015 and 2016, at least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- *Denominator*: Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of the eligible hospital or CAH during the EHR reporting period.

- *Numerator*: The number of patients (or patient-authorized representative) in the denominator who view, download, or transmit to a third party their health information.

- *Threshold*: The numerator and denominator must be reported and the numerator must be equal to or greater than 1.

- *Exclusion*: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

For an EHR reporting period in 2017, more than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) view, download or transmit to a third party their health information during the EHR reporting period.

- *Denominator*: Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of the eligible hospital or CAH during the EHR reporting period.

- *Numerator*: The number of patients (or patient-authorized representative) in the denominator who view, download,

or transmit to a third party their health information.

- *Threshold*: The resulting percentage must be greater than 5 percent.

- *Exclusion*: Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Alternate Exclusion: Providers may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

We are adopting Objective 8: Patient Electronic Access at § 495.22(e)(8)(i) for EPs and § 495.22(e)(8)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 9: Secure Electronic Messaging (EP Only)

We proposed to retain the EP Stage 2 objective for secure electronic messaging with modifications to the measure for meaningful use in 2015 through 2017.

Proposed Objective: Use secure electronic messaging to communicate with patients on relevant health information.

Proposed Measure: The capability for patients to send and receive a secure electronic message with the provider was fully enabled during the EHR reporting period.

We proposed to retain the exclusion for EPs who have no office visits and for those EPs who lack the infrastructure required for secure electronic messaging due to being located in areas with limited broadband availability as identified by the Federal Communications Commission (FCC).

Exclusion: Any EP who has no office visits during the EHR reporting period, or any EP who conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We proposed that an EP scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may claim an exclusion for the secure electronic messaging objective measure as there is not an equivalent Stage 1 objective or measure defined at 42 CFR 495.6.

- *Alternate Exclusion*: An EP may claim an exclusion for the measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

We proposed no alternate specifications for this objective and there is no equivalent objective for eligible hospitals and CAHs in the Stage 2 objectives and measures for meaningful use.

Comment: Some commenters expressed their general support for secure messaging, stating their appreciation for the convenience and ease with messaging their EPs electronically. Numerous commenters also agreed with exclusions for EPs with no office visits during the EHR reporting period and recommended a higher number than zero. A commenter expressed support for the alternate exclusion and requested the extension of this exclusion beyond 2015.

Commenters expressing general opposition to secure messaging cited their patients' reluctance to sign up for the portal due to data breach fears, lack of internet familiarity, and overall lack of access. Other commenters also recommended continuing the reduced requirement in the future.

Response: We thank the commenters for their insight. We believe that given the proposed changes to the measure, the current exclusions are adequate and that the proposed alternate exclusion does not need to be extended beyond 2015.

Comment: Many commenters disagreed with the proposal to lower the threshold, with some believing that it takes momentum away from patient engagement. Some commenters conflated the proposals and stated the same concerned opposition for secure messaging as for the patient action measure discussed in section II.B.2.a.(viii) stating that "one patient" for secure messaging is not meaningful enough.

Response: We appreciate the commenters' advocacy for patients and applaud their efforts to promote patient engagement and raise awareness about the need for accessibility of health

information. We agree with the intent behind the policy and support the policy goal of promoting enhanced patient and provider engagement, and leveraging HIT solutions to enhance patient and provider communications. We direct readers to the proposed measure we included for the Stage 3 Objective for Coordination of Care through Patient Engagement in section II.B.2.b.vi of this final rule with comment period. We would like to highlight some key differences between the Stage 3 proposed objective and the current objective, which are the result of lessons learned through feedback over the past few years from providers about their efforts to implement the requirements of the EHR Incentive Program. We believe this will help to illustrate why we proposed to reduce the threshold for this Secure Messaging objective and how we are seeking to maintain the policy of moving patient engagement forward.

As noted in the Stage 3 proposed rule (80 FR 16756) and for the Stage 3 objective in section II.B.2.b.vi of this final rule with comment period, we included proposals for bi-directional communication and communications among and between the patient and multiple providers in a care team. We also expanded the potential role of patient-authorized representatives, and we sought to adopt a wider range of communications methods that could support and promote patient-centered care coordination. We proposed this objective because we believe that leveraging health IT to support care team communications in which a patient is actively engaged can lead to better care coordination and better outcomes for the patient. However, the current Stage 2 secure messaging objective as finalized in the 2012 Stage 2 final rule (77 FR 54031) does not include this flexibility of form, method and participation. It includes only patient-initiated communication rather than provider driven engagement, and it does not promote a wide range of use cases. Comments received indicate that this is a significant shortfall in the language of the current measure supporting the identified health care delivery system reform goal. In addition, commenters note that these factors and other environmental or patient related factors create a significant burden on providers and negatively impact a provider's ability to meet the measure. This means that providers are investing a large amount of resources to achieve a measure that is flawed, does not adequately meet the intended health goal, and provides only a limited value.

We believe that the measure should be modified to better serve as a foundation for a more dynamic use of HIT for patient engagement. For this reason, we proposed to continue support of the function and to adopt a more dynamic measure for Stage 3 that will help drive adoption and innovation to support the long-term goals of leveraging HIT for patient engagement.

Comment: General recommendations from commenters included encouraging greater definition around secure messaging, allowing for texting/voicemail/other options, adding more exclusions, and taking into consideration patients' preferences for communication with their EPs. Some commenters requested clarification on what we consider "fully enabled" when it comes to secure messaging.

In addition, some commenters opposed lowering the threshold believe that removing the current thresholds will not help or encourage providers to prepare for upcoming Stage 3 thresholds. These commenters recommended that we consider an incrementally phased-in approach towards measure thresholds to balance the challenges providers face in promoting patient engagement. These commenters suggested beginning with simple enabled functions as proposed and increasing the threshold incrementally year over year to work toward the proposed Stage 3 threshold of 35 percent rather than having a static low threshold and a sudden jump to a higher level in Stage 3.

Still other commenters requested expanding the definition of secure messaging in the current objective to reflect the options and methods proposed for the Stage 3 objective. These commenters requested that provider initiated messaging should be the action that counts toward the numerator for the current objective and that communications with a patient-authorized representative on the patient's behalf should also count toward the measure.

Response: Fully enabled means the function is fully installed, any security measures are fully enabled, and the function is readily available for patient use. We note that we have proposed no changes to the definition of secure messaging for this measure or to any of the exclusions apart from the proposed alternate exclusion for Stage 1 providers in 2015. We proposed to remove the Stage 2 threshold of 5 percent and instead require that the capability for patients to send and receive a secure electronic message is fully enabled during the EHR reporting period (80 FR 20365). However, we agree with

commenters' recommendations for a phased in approach over the period of 2015 through 2017 to the Stage 3 threshold in 2018, as it will allow providers to work incrementally toward a high goal and is consistent with our past policy in the program to establish incremental change from basic to advanced use and increased thresholds over time. We will therefore finalize "fully enabled" for 2015, at least one patient for 2016, and a threshold of 5 percent for 2017 to build toward the Stage 3 threshold addressed in section II.B.2.b.6 of this final rule with comment period.

We cannot fully adopt the Stage 3 specifications as the commenters recommend because some parts, such as communications among care team members, would not be supported by EHR technology certified to the 2014 Edition certification criteria. However, we agree that it makes sense to focus the measure on provider action rather than on patient action and to allow provider initiated actions to be included in the numerator. As noted previously, we believe that a measure that more accurately reflects the policy goal for delivery system reform should include these provider initiated actions and we also agree with the inclusion of interactions involving a patient-authorized representative as this is an important factor for many patients in coordinating care. We will therefore modify the current objective to include provider initiated communications and communications with a patient-authorized representative in the numerator. We note that this change also means that a patient-initiated message would only count toward the numerator if the provider responded to the patient as that is part of measuring the provider action rather than the patient action for this measure. As this measurement would not be required until 2016 and then at a level of only 1 patient, we believe it is reasonable to make this change in the counting methodology in the current objective.

Comment: Some commenters stated a belief that the unique patient measures, including secure messaging, should be able to pull data from any time period before the reporting period and reporting year in order to qualify in the numerator. These commenters noted that this clarification would reduce the unnecessary burden placed on physicians, and the waste of resources to provide the patient with the same information they have already been provided.

Response: We do not believe a single instance of a patient sending a secure message should be counted in

perpetuity for the measure. The calculation may include actions taken before, during, or after the EHR reporting period if the period is less than one full year; however, consistent with FAQ 8231, these actions must be taken no earlier than the start of the same year as the EHR reporting period and no later than the date of attestation. We understand, as discussed in section II.B.1.b.(4)(f), that some certified EHRs may not calculate the numerator in this fashion; however, as we are also changing the threshold for the measure so that significant measurement will not be required until 2016 and then at a required level of only 1 patient, we believe that changing this calculation will not drastically impact EHR developers and providers.

After consideration of the comments received, we are finalizing as proposed the objective, exclusion, and alternate exclusion as proposed. We are finalizing the measure with the modifications to the thresholds. We are adopting the objective as follows:

Objective 9: Secure Electronic Messaging (EP Only)

EP Objective: Use secure electronic messaging to communicate with patients on relevant health information.

EP Measure: For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled during the EHR reporting period.

For an EHR reporting period in 2016, for at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.

- *Numerator:* The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative).

- *Threshold:* The numerator and denominator must be reported, and the numerator must be equal to or greater than 1.

For an EHR reporting period in 2017, for more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the

patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.

- *Denominator:* Number of unique patients seen by the EP during the EHR reporting period.

- *Numerator:* The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative).

- *Threshold:* The resulting percentage must be more than 5 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period, or any EP who conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Alternate Exclusion:

Alternate Exclusion: An EP may claim an exclusion for the measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

We are adopting Objective 9: Secure Electronic Messaging at § 495.22(e)(9)(i) for EPs. We further specify that in order to meet this objective and measures, an EP must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 10: Public Health and Clinical Data Registry Reporting

In the EHR Incentive Programs in 2015 through 2017 proposed rule 80 FR 20366, we proposed to adopt a modified version of the consolidated Public Health and Clinical Data Registry Reporting objective proposed in the Stage 3 proposed rule for all providers to demonstrate meaningful use for an EHR reporting period in 2015 through 2017.

Proposed Objective: The EP, eligible hospital or CAH is in active engagement with a Public Health Agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except

where prohibited and in accordance with applicable law and practice.

In the EHR Incentive Programs for 2015 through 2017 proposed rule 80 FR 20366, we highlighted our intention to align with the Stage 3 proposed rule and remove the prior ongoing submission requirement and replace it with an “active engagement” requirement. We reiterated our definition of “active engagement” as defined in the Stage 3 proposed rule at (80 FR 16739 and 16740) and noted our proposal to adopt the same definition for the Modified Stage 2 objective proposed for 2015 through 2017 as we believe this change is more aligned with the process providers undertake to report to a clinical registry or public health agency.

At (80 FR 20366), we proposed that “active engagement” may be demonstrated by any of the following options:

Proposed Active Engagement Option 1—Completed Registration to Submit Data:

The EP, eligible hospital or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, eligible hospital, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Proposed Active Engagement Option 2—Testing and Validation:

The EP, eligible hospital, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

Proposed Active Engagement Option 3—Production:

The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

We noted that the change in definition is intended to better capture the activities a provider may conduct in order to engage with a PHA or CDR, and that any prior action taken to meet the non-consolidated public health reporting objectives of meaningful use Stages 1 and 2 would count toward

meeting the active engagement requirement of this objective.

Comment: Many commenters expressed concern regarding whether provider and developers would have adequate time to implement a new active engagement requirement in place of the ongoing submission requirement in time to successfully attest for an EHR reporting period in 2015.

Response: We note that while the active engagement options included in the EHR Incentive Program for 2015 to 2017 replace the “ongoing submission” requirement included in the Stage 2 final rule, they should not be considered mutually exclusive. We note that for providers who have already planned for and/or acted toward meeting any of the Stage 1 or Stage 2 public health reporting objectives, those actions would count toward meeting the active engagement options.

For clarification on the rationale behind this change, we note that over the past few years, we have received feedback on the Stage 1 and Stage 2 public health reporting objectives through letters, public forums, and individual inquiries from both providers/provider representatives and from public health agencies. The common trend in these communications is that the difference between the Stage 1 and Stage 2 requirements and the “ongoing submission” structure for the Stage 2 objectives created confusion around both the actions required and the timing of those actions for providers. The active engagement requirement clarifies what is expected of a provider who seeks to meet the measures within this objective and more accurately describes the actions necessary to meet each option within the structure. This does not mean that actions a provider has already taken in an attempt to meet the “ongoing submission” requirement would not be acceptable under the new objective. Any action which would be acceptable under the Stage 1 and Stage 2 public health reporting objectives would fit within the definition of the “active engagement” options. In addition, because of the similarity between the substantive requirements of the “ongoing submission” requirement and the “active engagement” requirement options included in this final rule with comment period, we do not believe that significant time will be needed to implement the updated requirement.

For example, in Stage 2 a provider could register their intent to submit data to successfully meet a measure in one of the public health reporting objectives. Our proposal in the EHR Incentive Programs for 2015 through 2017

proposed rule includes the exact same requirement under “Active Engagement Option 1: Completed Registration to Submit Data.”

We also believe that the flexibility within the active engagement options enables a provider additional time to determine the option that is best suited to their practice. For example, in Active Engagement Option 1, we also proposed that a provider would be required to register to submit data to the PHA within 60 days of the beginning of the EHR reporting period and not on the first day of the EHR reporting period. We believe that this 60-day timeframe will benefit providers who seek to determine whether Option 1 best captures their reporting status, or whether Option 2 or Option 3 are more appropriate. We further note that this requirement would allow a provider to begin their registration prior to the start of their EHR reporting period if such were necessary, so long as the action was completed within 60 days of the start of the EHR reporting period.

Comment: Commenters requested clarification on whether a provider needed to register each year under the active engagement option 1. Commenters noted that requiring registration each year would result in duplicative registrations. Commenters also requested clarity on whether registration is required for each measure. A commenter noted that they recommend that clarity be provided regarding whether registration is required for measures that the provider has not registered for previously (for example, measures not included in Stage 2).

Response: As we have noted elsewhere in this final rule with comment period, under the proposed active engagement requirement, providers would only need to register once with a public health agency or a clinical data registry and could register before the reporting period begins. In addition, we note that previous registrations with a public health agency or clinical data registry that occurred in a previous stages of meaningful use could count toward Active Engagement Option 1 for any of the EHR reporting periods in 2015, 2016, or 2017. We clarify that providers must register with a PHA or CDR for each measure they intend to use to meet meaningful use. Further, we also clarify that to meet Active Engagement Option 1, registration with the applicable PHA or CDR is required where a provider seeks to meet meaningful use using a measure they have not successfully attested to in a previous EHR reporting period.

Comment: Commenters also requested clarification regarding whether a provider can successfully attest to meaningful use using proof of active engagement collected by their organization, or whether a provider must demonstrate that they independently engaged with the PHA or CDR.

Response: Providers can demonstrate meaningful use by using communications and information provided by a PHA or CDR to the provider directly. A provider also may demonstrate meaningful use by using communications and information provided by a PHA or CDR to the practice or organization of the provider as long as the provider shares the same CEHRT as the practice or organization.

Comment: Some comments requested clarification of the definition of production under Active Engagement Option 3.

Response: To meet any of the measures using Active Engagement—Option 3 (production), we proposed that a provider only may successfully attest to meaningful use when the receiving PHA or CDR moves the provider into a production phase. We recognize that live data may be sent during the Testing and Validation phase of Active Engagement: Option 2, but-in such a case the data received in Option 2 is insufficient for purposes of meeting Option 3 unless the PHA and CDR is actively accepting the production data from the provider for purpose of reporting.

Proposed Measures: We proposed a total of six possible measures for this objective. For meaningful use in 2015 through 2017, EPs would be required to choose from Measures 1 through 5, and would be required to successfully attest to any combination of two measures. For meaningful use in 2015 through 2017, eligible hospitals, and CAHs would be required to choose from Measures 1 through 6, and would be required to successfully attest to any combination of three measures. In 2015 only for providers scheduled to be in Stage 1, EPs would be required to choose from Measures 1 through 5, but would be permitted to successfully attest to one measure; and eligible hospitals and CAHs would be required to choose from Measures 1 through 6, but would be permitted to successfully attest to any combination of two measures. The proposed measures are as shown in Table 5. We proposed that measures 4 and 5 for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public

Health Registry or Clinical Data Registry is available.

TABLE 5—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting	1	1
Measure 2—Syndromic Surveillance Reporting	1	1
Measure 3—Case Reporting	1	1
Measure 4—Public Health Registry Reporting*	2	3
Measure 5—Clinical Data Registry Reporting**	2	3
Measure 6—Electronic Reportable Laboratory Results	N/A	1

* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.

** EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

For EPs, we proposed that an exclusion for a measure does not count toward the total of two measures. Instead, in order to meet this objective an EP would need to meet two of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than two, the EP can meet the objective by meeting the one remaining measure available to them and claiming the applicable exclusions. If no measures remain available, the EP can meet the objective by claiming applicable exclusions for all measures. An EP who is scheduled to be in Stage 1 in 2015 must report at least one measure unless they can exclude from all available measures. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we proposed that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective, an eligible hospital or CAH would need to meet three of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than three, the eligible hospital, or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. If no measures remain available, the eligible hospital or CAH can meet the objective by claiming applicable exclusions for all measures. An eligible hospital or CAH that is scheduled to be in Stage 1 in 2015 must report at least two measures unless they can—either;—(1) Exclude from all but one available measure and report that one measure; or (2) can exclude from all

available measures. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

We note that we proposed to allow EPs, eligible hospitals, and CAHs to choose to report to more than one public health registry to meet the number of measures required to meet the objective. We also proposed to allow EPs, eligible hospitals, and CAHs to choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

Comment: Commenters requested clarification regarding the number of measures that a provider would be required to meet for the EHR reporting periods covered by the EHR Incentive Program in 2015 through 2017 requirements.

Response: In the EHR Incentive Program for 2015 through 2017 proposed rule (80 FR 20356), we proposed that for providers scheduled to attest to Stage 1 in 2015, EPs would be required to successfully attest to one measure and eligible hospitals and CAHs would be required to successfully attest to any combination of two measures. We also proposed that for providers scheduled to attest to Stage 2 in 2015 and for all providers in 2016 and 2017, EPs would be required to successfully attest to any combination of two measures and eligible hospitals and CAHs would be required to successfully attest to any combination of three measures. Finally, we proposed that EPs may select from measures 1 through 5 while eligible hospitals and CAHs may select from measures 1 through 6.

To calculate the measures:
 • *Proposed Measure 1—Immunization Registry Reporting:* The EP, eligible hospital, or CAH is in active engagement with a public health agency

to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

We proposed that to successfully meet the requirements of this measure, bi-directional data exchange between the provider’s CEHRT system and the immunization registry/IIS is required.

Exclusion: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH—

++ Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction’s immunization registry or immunization information system during the EHR reporting period;

++ Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the EP, eligible hospital, or CAH at the start of the EHR reporting period.

Comment: For Measure 1—Immunization Registry Reporting, the vast majority of commenters noted that the addition of bi-directionality during the EHR Incentive Program 2015 through 2017 period would be burdensome to accomplish. A commenter noted that bi-directional capability is newly proposed for Stage 3 and as part of the 2015 Edition proposed rule, and is not currently part of the

Stage 2 or 2014 Edition rule requirements. The commenter noted that adding in this requirement would require significant development and implementation effort and that most states are not yet able to engage in this functionality.

Response: We appreciate commenters' concerns regarding the addition of a bi-directionality requirement for the EHR reporting periods covered by the modified Stage 2 requirements. We agree with commenters that additional time may be needed for both public health agencies and providers to adopt the necessary technology to support bi-directional functionality. Therefore, we are not finalizing the bi-directionality proposal in the EHR Incentive Programs for 2015 through 2017.

- *Proposed Measure 2—Syndromic Surveillance Reporting:* The EP, eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting where the jurisdiction accepts syndromic data from such settings and the standards are clearly defined for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).

Exclusion for EPs: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP—

- ++ Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in his or her jurisdiction;

- ++ Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

- ++ Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

Exclusion for eligible hospitals/CAHs: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH—

- ++ Does not have an emergency or urgent care department;

- ++ Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

- ++ Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

Comment: For Measure 2—Syndromic Surveillance Reporting, many commenters noted that jurisdictions are not able to receive ambulatory syndromic surveillance data and that, the standards for ambulatory syndromic surveillance in 2014 CEHRT for reporting are vague. A comment noted that few PHAs appear to be able to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically. These commenters recommended that the syndromic surveillance measure should be removed from the objective.

Response: We disagree with commenters who suggest that the syndromic surveillance measure should be removed from the EHR Incentive Programs for 2015 through 2017. While some jurisdictions are not currently accepting syndromic surveillance data from ambulatory care providers, there are other providers who have been able to report in their jurisdictions and who have successfully attested to this measure. We believe that removing the syndromic surveillance measure as an option would negatively impact such providers. We also believe that maintaining this measure for 2015 through 2017 allows additional providers to choose this measure in the future. We remind commenters that syndromic surveillance reporting is one option available to providers. If this option is not suitable for the provider, additional options are available and exclusions for this measure are also available. We are modifying the proposed EP exclusion which states “does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in his or her jurisdiction” to better indicate that the registry may or may not allow the EP to report based on their category rather than on whether they treat or diagnose specific diseases or condition for syndromic surveillance reporting. For eligible hospitals and CAHs, almost all jurisdictions currently accept syndromic surveillance data. Finally, we note that some eligible professionals are already submitting syndromic surveillance data which is allowable under Stage 2. Therefore, we are adopting a modification that allows all eligible professionals to submit syndromic surveillance data for an EHR reporting period in 2015 through 2017.

- *Proposed Measure 3—Case Reporting:* The EP, eligible hospital, or

CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

Proposed Exclusions: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH—

- ++ Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period;

- ++ Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

- ++ Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

Comment: Some commenters noted that case reporting is not mature enough to be included in meaningful use for 2015, 2016, or 2017. A commenter noted that the majority of eligible providers operate in jurisdictions where PHAs are not able to receive electronic case reporting data and have not developed the infrastructure to support such reporting. The commenters noted that the 2015 Edition proposed rule does not include certification criteria on case reporting. These commenters recommended removing this measure from the objective for 2015 through 2017.

Response: We appreciate commenter concerns regarding the readiness of standards and functionality for case reporting and believe that technology may not yet be sufficiently mature. Based on public comment received, it is clear that many public health jurisdictions have not yet built the infrastructure to receive electronic case reports, and while a few public health jurisdictions have infrastructure to accept case reports, many of these are not able to accept case reports in a standard format. Building new infrastructure to support electronic case reporting across multiple public health jurisdictions and to support certification may not be feasible for EHR Incentive Program reporting periods in 2015, 2016, and 2017. We continue to believe that case reporting is a core component of public health reporting and to health improvement around the country and, as noted elsewhere, are maintaining this measure for Stage 3. However, for purposes of the EHR Incentive Program for 2015 through 2017, we believe

additional time is needed across the HIT landscape to develop the technology and infrastructure to support case reporting and we are not finalizing this measure as proposed.

If a provider chooses to participate in Stage 3 in 2017, they must meet the requirements defined for the Stage 3 Public Health and Clinical Data Registry Reporting objective which may include the case reporting measure defined for the Stage 3 objectives discussed in section II.B.2.b.viii of this final rule with comment period.

- **Proposed Measure 4—Public Health Registry Reporting:** The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

As noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20368), in the Stage 2 final rule, we were purposefully general in our use of the term “specialized registry” (other than a cancer registry) for the Stage 2 Specialized Registry Reporting Objective to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and responses to a **Federal Register** notice soliciting public comments on the proposed information collections to develop a centralized repository on public health readiness to support meaningful use (79 FR 7461); we proposed to carry forward the concept behind this broad category from Stage 2, but also proposed to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20367). We proposed to define a “public health registry” as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we proposed to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023).

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR

20367), we reiterated that any EP, eligible hospital, or CAH may report to more than one public health registry to meet the total number of required measures for the objective. For example, if a provider meets this measure through reporting to both the National Hospital Care Survey and the National Healthcare Safety Network registry, the provider could get credit for meeting two measures.

We further noted that ONC adopted standards for ambulatory cancer case reporting in its 2014 Edition final rule (see § 170.314(f)(6)) and CMS provided EPs the option to select the cancer case reporting menu objective in the Stage 2 final rule (77 FR 54029 through 54030). We included cancer registry reporting as a separate objective from specialized registry reporting because it was more mature in its development than other registry types, not because other reporting was intended to be excluded from meaningful use. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20369), we proposed that EPs would have the option of counting cancer case reporting under the public health registry reporting measure, but that cancer case reporting is not an option for eligible hospitals and CAHs, because hospitals have traditionally diagnosed and treated cancers (or both) and have the infrastructure needed to report cancer cases.

Proposed Exclusions: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH—

- ++ Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period;

- ++ Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

- ++ Operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Comment: Some commenters noted that for Measure 4—Public Health Registry Reporting, public health registries that would fall within this measure would need additional time to implement the applicable standards identified in the 2015 Edition rule, which would be applicable to providers

seeking to attest to meaningful use in 2015, 2016, or 2017. Commenters specifically noted that the certification requirements for public health registries are not identified in the 2014 Edition rule and that the technology and infrastructure to support such registries is not yet mature.

Many commenters recommended changing this measure and the clinical data registry reporting measure back to the prior Stage 2 requirements for the specialized registry reporting objective for 2015 through 2017 instead of splitting that objective into two measures as proposed. Commenters noted that if the language in the Stage 2 specialized registry reporting objective were changed to include the “Active engagement” definition, it would provide a wide range of options which offers a value for providers and especially for certain EP specialties who may otherwise be excluding from all available measures. In addition, commenters note that maintaining the existing specialized registry reporting objective would provide continuity for providers and not inadvertently penalize providers who had selected to report to a registry under the specialized registry reporting objective which may not qualify under the definition of a public health registry or a clinical data registry from the proposed rule.

Response: We appreciate commenters concerns regarding the public health registry reporting measure proposed. We agree that the standards for public health registry reporting are part of the 2015 Edition rule and are not currently part of 2014 Edition Rule that providers are required to use in 2015 and may use in 2016 and 2017. We understand commenter concerns that requiring public health registry reporting could present a challenge for developers and for public health jurisdictions seeking to support such reporting. Furthermore, we agree that our proposal to split the Specialized Registry Reporting objective into two measures may inadvertently cause some providers to no longer use their current reporting option to meet the measure. We are therefore not finalizing our proposal to split specialized registry reporting into two measures as proposed.

Instead, we will maintain for 2015 through 2017 a unified specialized registry reporting measure which adopts the change from “ongoing submission” to “active engagement”. We believe that this will allow providers flexibility to continue in the direction they may have already planned for reporting while still allowing for a wide range of reporting options in the future. We further note that we have previously supported the

inclusion of a variety of registries under the specialized registry measure, including Prescription Drug Monitoring Program reporting and electronic case reporting. We agree that a variety of registries may be considered specialized registries, which allows providers the flexibility to report using a registry that is most helpful to their patients. Therefore, we will continue to allow these registries to be considered specialized registries for purposes of reporting the EHR Reporting period in 2015, 2016, and 2017. However, we will modify the exclusion not only to reflect the change from public health registry to specialized registry but also to allow an exclusion if the provider does not collect the data relevant to a specialized registry within their jurisdiction.

We are also finalizing our proposed policy to incorporate cancer case reporting into the measure for EPs only. Therefore, EPs who were previously planning to attest to the cancer case reporting objective, may count that action toward the Specialized Registry Reporting measure. We believe this change is necessary to support continued provider reporting to cancer case registries. However, we note that EPs who did not intend to attest to the cancer case reporting menu objective are not required to engage in or exclude from cancer case reporting in order to meet the specialized registry reporting measure. We further note that providers may use electronic submission methods beyond the functions of CEHRT to meet the requirements for the Specialized Registry Reporting measure. Finally, we are adopting our proposal that providers may count the measure more than one time if they report to multiple specialized registries as proposed. For the Stage 3 public health registry reporting measure within the Public Health and Clinical Data Registry Reporting Objective, we direct readers to section II.B.2.b.viii of this final rule with comment period.

• **Proposed Measure 5—Clinical Data Registry Reporting:** The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

As discussed in the Public Health Registry Reporting measure, we proposed to split specialized registry reporting into two separate, clearly defined measures: Public health registry reporting and clinical data registry reporting. In Stage 2 for EPs, reporting to specialized registries is a menu objective and this menu objective includes reporting to clinical data registries. For Stage 3, we proposed to include clinical data registry reporting as an independent measure. The

National Quality Registry Network defines clinical data registries as those that record information about the health status of patients and the health care they receive over varying periods of time^[1]. We proposed to further differentiate between clinical data registries and public health registries as follows: For the purposes of meaningful use, “public health registries” are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and, “clinical data registries” are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by PHAs but that are important to a specialist’s provision of care. Clinical data registries can also be used to monitor health care quality and resource use.

We proposed that any EP, eligible hospital, or CAH may report to more than 1 clinical data registry to meet the total number of required measures for this objective. ONC would consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the CEHRT definition as it relates to meeting the clinical data registry reporting measure through future rulemaking for the EHR Incentive Programs.

Exclusion: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH—

++ Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period;

++ Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Comment: Some commenters noted that for Measure 5—Clinical Data Registry Reporting, the potential

registries will need additional time to implement the applicable standards in the 2015 Edition rule. Other commenters disagreed with our proposal to split the Specialized Registry Reporting Objective into two measures for reporting in 2015 through 2017 citing unintended negative consequences on providers who have planned for and acted toward meeting the prior requirements, especially on the short term in 2015 and 2016. These commenters recommended retaining the prior specifications for the objective instead of adopting two new measures.

Response: We agree that the standards for clinical data registry reporting are not currently part of the 2014 CEHRT definition requirements and understand commenter concerns that without clarity on the functionality needed to support this measure, it would be difficult for providers to implement. As noted in relation to the proposed public health reporting measure, we also agree with commenters who state that there would potentially be unintended negative consequences for providers in 2015 and 2016 especially if we adopt the proposal to split the Specialized Registry Reporting Objective into two separate measures. As noted previously, we are not adopting this policy for the public health reporting measure, and we are also therefore not adopting the policy for a separate clinical data registry reporting measure. We are therefore not adopting this measure as proposed.

As noted previously, we are not finalizing our proposal to split the measure from the Stage 2 Specialized Registry Reporting Objective (77 FR 54030) into two measures. Therefore, we are not finalizing the clinical data registry reporting measure for 2015, 2016, and for 2017 for those providers who are not demonstrating Stage 3. If a provider chooses to participate in Stage 3 in 2017, they must meet the requirements defined for the Stage 3 Public Health and Clinical Data Registry Reporting objective as discussed in section II.B.2.b.viii of this final rule with comment period.

• **Proposed Measure 6—Electronic Reportable Laboratory Result Reporting:** The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory (ELR) results. We proposed this measure for eligible hospitals and CAHs only.

Exclusion: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH—

++ Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period;

++ Operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from eligible hospitals or CAHs at the start of the EHR reporting period.

Comment: For Measure 6—ELR, commenters agreed with the continuation of this measure but requested that it also be included as an option for EPs that maintain in-house laboratories.

Response: We thank commenters for their support of this measure. However, we do not agree that this measure should be extended to EPs. We note that in-house laboratories of EPs do not perform the types of tests that are reportable to public health jurisdictions. For example, many in-house laboratories focus on tests such as rapid strep tests that test for strep throat. The rapid strep tests are not reportable to public health agencies.

After consideration of public comments received, for EHR reporting periods in 2015 through 2017, we are finalizing the objective with a modification to the name to state Public Health Reporting Objective and to remove the reference to clinical data registries. We are finalizing the measures with modifications. For Measure 1, we remove the requirement for bi-directional data exchange and note that providers will not be required to receive a full immunization history and will not be required to display an immunization forecast from an Immunization Information System (IIS) to meet the measure. Providers will only need to electronically submit immunization data to the appropriate public health jurisdiction's IIS. For Measure 2, we are adopting a modification to the final policy to allow all EPs to submit syndromic surveillance data and to modify the exclusions to reflect that different categories of providers may or may not be able to report based on the requirements of the registry. For Measure 3, we are not finalizing the proposed case reporting measure. For Measure 4, we are not finalizing our proposal to split specialized registry reporting into two distinct measures. Instead, we will maintain a unified specification for specialized registry

reporting which adopts the change from “ongoing submission” to “active engagement” and includes reporting for eligible hospitals and CAHs for 2015 through 2017. We include cancer case reporting as an option for EPs only under the adopted specialized registry reporting measure. We are redesignating this measure as “Measure 3”. For Measure 5, we are not finalizing the proposed clinical data registry reporting measure. For Measure 6, we are finalizing the measure language as proposed and redesignating the measure as “Measure 4”.

For the explanation of terms, we are finalizing the definition of active engagement with the additional clarification provided through response to public comment. We are finalizing that EPs must meet at least 2 measures with a modification to reference the selection from measures 1 through 3 (rather than 1 through 5). Similarly, we are finalizing that eligible hospitals and CAHs must meet at least 3 measures from measures 1 through 4 (rather than 1 through 6). We are also finalizing the alternate specification that in 2015 Stage 1 EPs may meet one measure to meet the threshold and Stage 1 eligible hospitals and CAHs may meet two measures to meet the threshold.

For EPs, we are finalizing that an exclusion for a measure does not count toward the total of two measures. Instead, in order to meet this objective an EP would need to meet two of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than two, the EP can meet the objective by meeting the one remaining measure available to them and claiming the applicable exclusions. If no measures remain available, the EP can meet the objective by claiming applicable exclusions for all measures. An EP who is scheduled to be in Stage 1 in 2015 must report at least one measure unless they can exclude from all available measures. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we are finalizing that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective an eligible hospital or CAH would need to meet three of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than three, the eligible hospital or CAH can meet the objective by meeting all of the remaining measures

available to them and claiming the applicable exclusions. If no measures remain available, the eligible hospital or CAH can meet the objective by claiming applicable exclusions for all measures. An eligible hospital or CAH that is scheduled to be in Stage 1 in 2015 must report at least two measures unless they can either—(1) Exclude from all but one available measure and report that one measure; or (2) can exclude from all available measures. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

Finally, we note that a provider may report to more than one specialized registry and may count specialized registry reporting more than once to meet the required number of measures for the objective.

We are adopting the final objective, measures, exclusions, and alternate specification as follows:

Objective 10: Public Health Reporting

Objective: The EP, eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT except where prohibited and in accordance with applicable law and practice.

Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data.

Exclusion: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH—

- Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period;
- Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

- Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the EP, eligible hospital, or CAH at the start of the EHR reporting period.

Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data.

Exclusion for EPs: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP—

- Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction’s syndromic surveillance system;
- Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or
- Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

Exclusion for eligible hospitals/CAHs: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH—

- Does not have an emergency or urgent care department;
- Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition

at the start of the EHR reporting period; or

- Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

*Measure 3—Specialized Registry Reporting—*The EP, eligible hospital, or CAH is in active engagement to submit data to a specialized registry.

Exclusions: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the specialized registry reporting measure if the EP, eligible hospital, or CAH—

- Does not diagnose or treat any disease or condition associated with or collect relevant data that is required by a specialized registry in their jurisdiction during the EHR reporting period;
- Operates in a jurisdiction for which no specialized registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or
- Operates in a jurisdiction where no specialized registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic

registry transactions at the beginning of the EHR reporting period.

Measure 4—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory (ELR) results.

Exclusion: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH—

- Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period;
 - Operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or
 - Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from eligible hospitals or CAHs at the start of the EHR reporting period.
- Alternate Specification:* An EP scheduled to be in Stage 1 in 2015 may meet 1 measure and an eligible hospital or CAH scheduled to be in Stage 1 in 2015 may meet two measures.

TABLE 6—PUBLIC HEALTH REPORTING OBJECTIVE MEASURES FOR EPS, ELIGIBLE HOSPITALS, AND CAHs IN 2015 THROUGH 2017

Measure number and name	Measure specification	Maximum times measure can count towards the objective
Measure 1—Immunization Registry Reporting.	The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data.	1.
Measure 2—Syndromic Surveillance Reporting.	The EP, eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data.	1.
Measure 3—Specialized Registry Reporting.	The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to a specialized registry.	2 for EP, 3 for eligible hospital/CAH.
Measure 4—Electronic Reportable Laboratory Results Reporting.	The eligible hospital or CAH is in active engagement with a public health agency to submit ELR results.	N/A.

We are adopting Objective 10: Public Health Reporting at § 495.22(e)(10)(i) for EPs and § 495.22(e)(10)(ii) for eligible hospitals and CAHs. We further specify that providers must use the functions and standards as defined for CEHRT at

§ 495.4 where applicable; however, as noted for measure 3, providers may use functions beyond those established in CEHRT in accordance with state and local law. We direct readers to section II.B.3. of this final rule with comment

period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

TABLE 7—ELIGIBLE PROFESSIONAL (EP) OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017

Objectives for 2015, 2016 and 2017	Measures for providers in 2015, 2016 and 2017	Alternate exclusions and/or specifications for certain providers
Objective 1: Protect Patient Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained by Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.	NONE.
Objective 2: Clinical Decision Support.	<ul style="list-style-type: none"> • <i>Measure 1:</i> Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. • <i>Measure 2:</i> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. 	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <p><i>Alternate Objective and Measure 1:</i> <i>Objective:</i> Implement one clinical decision support rule relevant to specialty or high clinical priority, along with the ability to track compliance with that rule. <i>Measure:</i> Implement one clinical decision support rule.</p>
Objective 3: Computerized Provider Order Entry CPOE.	<ul style="list-style-type: none"> • <i>Measure 1:</i> More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry. • <i>Measure 2:</i> More than 30 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry. • <i>Measure 3:</i> More than 30 percent of radiology orders created by the EP during the EHR reporting period are recorded using computerized provider order entry. 	<ul style="list-style-type: none"> • <i>Alternate Measure 1:</i> For Stage 1 providers in 2015 only, more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP during the EHR reporting period during the EHR reporting period, are recorded using computerized provider order entry. • <i>Alternate Exclusion for Measure 2:</i> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016. • <i>Alternate Exclusion for Measure 3:</i> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016.
Objective 4: Electronic Prescribing.	<i>EP Measure:</i> More than 50 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	<i>Alternate EP Measure:</i> For Stage 1 providers in 2015 only, More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.
Objective 5: Health Information Exchange.	<i>Measure:</i> The EP that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.	<i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Summary of Care objective, which requires the electronic transmission of a summary of care document if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.
Objective 6: Patient-Specific Education.	<i>EP Measure:</i> Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.	<i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Patient-Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Patient-Specific Education menu objective.
Objective 7: Medication Reconciliation.	<i>Measure:</i> The EP, performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.	<i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.

TABLE 7—ELIGIBLE PROFESSIONAL (EP) OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Objectives for 2015, 2016 and 2017	Measures for providers in 2015, 2016 and 2017	Alternate exclusions and/or specifications for certain providers
Objective 8: Patient Electronic Access (VDT).	<ul style="list-style-type: none"> • <i>EP Measure 1:</i> More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information. • <i>EP Measure 2:</i> For 2015 and 2016: At least 1 patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits his or her health information to a third party during the EHR reporting period. For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits their health information to a third party during the EHR reporting period. 	<i>Alternate Exclusion Measure 2:</i> Providers may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.
Objective 9: Secure Messaging.	<p><i>Measure:</i> For 2015: For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled.</p> <p>For 2016: For at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative) during the EHR reporting period.</p> <p>For 2017: For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	<i>Alternate Exclusion:</i> An EP may claim an exclusion for the measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.
Objective 10: Public Health	<ul style="list-style-type: none"> • <i>Measure 1—Immunization Registry Reporting:</i> The EP is in active engagement with a public health agency to submit immunization data. • <i>Measure 2—Syndromic Surveillance Reporting:</i> The EP is in active engagement with a public health agency to submit syndromic surveillance data. <p><i>Measure 3—Specialized Registry Reporting:</i> The EP is in active engagement to submit data to a specialized registry.</p>	Stage 1 EPs in 2015 must meet at least 1 measure in 2015, Stage 2 EPs must meet at least 2 measures in 2015, and all EPs must meet at least 2 measures in 2016 and 2017.

TABLE 8—ELIGIBLE HOSPITAL AND CAH OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017

Objectives for 2015, 2016 and 2017	Measures for providers in 2015, 2016 and 2017	Alternate exclusions and/or specifications for certain providers
Objective 1: Protect Patient Health Information.	<p><i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the eligible hospital or CAHs risk management process.</p>	NONE.

TABLE 8—ELIGIBLE HOSPITAL AND CAH OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Objectives for 2015, 2016 and 2017	Measures for providers in 2015, 2016 and 2017	Alternate exclusions and/or specifications for certain providers
Objective 2: Clinical Decision Support.	<ul style="list-style-type: none"> • <i>Measure 1:</i> Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. • <i>Measure 2:</i> The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. 	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <p><i>Alternate Objective and Measure 1:</i> <i>Objective:</i> Implement one clinical decision support rule relevant to specialty or high clinical priority, along with the ability to track compliance with that rule. <i>Measure:</i> Implement one clinical decision support rule.</p>
Objective 3: Computerized Provider Order Entry CPOE.	<ul style="list-style-type: none"> • <i>Measure 1:</i> More than 60 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry. • <i>Measure 2:</i> More than 30 percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry. • <i>Measure 3:</i> More than 30 percent of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry. 	<ul style="list-style-type: none"> • <i>Alternate Measure 1:</i> For Stage 1 providers in 2015 only, more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP during the EHR reporting period during the EHR reporting period, are recorded using computerized provider order entry. • <i>Alternate Exclusion for Measure 2:</i> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016. • <i>Alternate Exclusion for Measure 3:</i> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016.
Objective 4: Electronic Prescribing.	<p><i>Eligible Hospital/CAH Measure:</i> More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.</p>	<p><i>Alternate EH Exclusion:</i> The eligible hospital or CAH may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2015 if they were either scheduled to demonstrate Stage 1, which does not have an equivalent measure, or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx objective for an EHR reporting period in 2015; and, the eligible hospital or CAH may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2016 if they were either scheduled to demonstrate Stage 1 in 2015 or 2016, or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx objective for an EHR reporting period in 2015.</p>
Objective 5: Health Information Exchange.	<p><i>Measure:</i> The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.</p>	<p><i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Summary of Care objective, which requires the electronic transmission of a summary of care document if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.</p>
Objective 6: Patient-Specific Education.	<p><i>Eligible Hospital/CAH Measure:</i> More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources identified by CEHRT.</p>	<p><i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Patient-Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Patient-Specific Education menu objective.</p>

TABLE 8—ELIGIBLE HOSPITAL AND CAH OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Objectives for 2015, 2016 and 2017	Measures for providers in 2015, 2016 and 2017	Alternate exclusions and/or specifications for certain providers
Objective 7: Medication Reconciliation.	<i>Measure:</i> The eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	<i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.
Objective 8: Patient Electronic Access (VDT).	<ul style="list-style-type: none"> • <i>Eligible Hospital/CAH Measure 1:</i> More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH are provided timely access to view online, download and transmit their health information to a third party their health information. • <i>Eligible Hospital/CAH Measure 2:</i> For 2015 and 2016: At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) views, downloads, or transmits to a third party his or her health information during the EHR reporting period. <p>For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period.</p>	<i>Alternate Exclusion Measure 2:</i> Provider may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.
Objective 9: Secure Messaging.	Not applicable for eligible hospitals and CAHs	Not applicable for eligible hospitals and CAHs.
Objective 10: Public Health	<ul style="list-style-type: none"> • <i>Measure 1—Immunization Registry Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data. • <i>Measure 2—Syndromic Surveillance Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data. • <i>Measure 3—Specialized Registry Reporting:</i> The eligible hospital, or CAH is in active engagement to submit data to a specialized registry. • <i>Measure 4—Electronic Reportable Laboratory Result Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit ELR results. 	Stage 1 eligible hospitals and CAHs must meet at least 2 measures in 2015, Stage 2 eligible hospitals and CAHs must meet at least 3 measures in 2015, all eligible hospitals and CAHs must meet at least 3 measures in 2016 and 2017.

b. Objectives and Measures for Stage 3 of the EHR Incentive Programs

Objective 1: Protect Patient Health Information

In the Stage 3 proposed rule at 80 FR 16745 through 16747, we noted that, consistent with HIPAA and its implementing regulations and both the Stage 1 and Stage 2 final rules (75 FR 44368 through 44369 and 77 FR 54002 through 54003), protecting electronic protected health information (ePHI) remains essential to all aspects of meaningful use under the EHR Incentive Programs. We remain cognizant that unintended or unlawful disclosures of ePHI could diminish consumer confidence in EHRs and the overall exchange of ePHI. Therefore, in both the Stage 1 and 2 final rules, we created a meaningful use core objective aimed at protecting patients' health care

information. Most recently, we finalized at (77 FR 54002 and 54003), a Stage 2 meaningful use core objective requiring providers to “protect ePHI created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.” The measure for this objective requires providers to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), implementing security updates as necessary, and correcting identified security deficiencies as part of the provider's risk management process. For further detail on this objective, we refer readers to the Stage 2 proposed and

final rules (77 FR 13716 through 13717 and 77 FR 54002).

In the Stage 3 proposed rule, we noted that public comments on the Stage 2 final rule and subsequent comments received through public forums, suggest some confusion remains among providers between the requirements of this meaningful use objective and the requirements established under 45 CFR 164.308(a)(1), 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3) of the HIPAA Security Rule. Although we stressed that the objective and measure finalized relating to ePHI are specific to the EHR Incentive Programs, and further added that compliance with the requirements in the HIPAA Security Rule falls outside the scope of this rulemaking, we nonetheless continued to receive inquiries about the relationship between our objective and the HIPAA Rules. Therefore, for Stage 3, in order to

alleviate provider confusion and simplify the EHR Incentive Program, we proposed maintaining the previously finalized Stage 2 objective on protecting ePHI. However, we proposed further explanation of the security risk analysis timing and review requirements for purposes of meeting this objective and associated measure for Stage 3.

Proposed Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

For the proposed Stage 3 objective, we added language to the security requirements for the implementation of appropriate technical, administrative, and physical safeguards. We proposed to include administrative and physical safeguards because an entity would require technical, administrative, and physical safeguards to enable it to implement risk management security measures to reduce the risks and vulnerabilities identified. Technical safeguards alone are not enough to ensure the confidentiality, integrity, and availability of ePHI. Administrative safeguards (for example, risk analysis, risk management, training, and contingency plans) and physical safeguards (for example, facility access controls, workstation security) are also required to protect against threats and impermissible uses or disclosures to ePHI created or maintained by CEHRT.

Comment: Most commenters supported the inclusion of this objective and many appreciate the addition of “administrative and physical safeguards” to the objective because it aligns with HIPAA. Most commenters appreciated our clarification of the timing and content of the security risk assessments. Several commenters appreciated the clarification that the requirements of this measure are narrower than what is required by HIPAA.

Some commenters noted in their support of the objective that it is essential for privacy protection and consumer confidence in EHRs as electronic personal health information is vulnerable to unauthorized access, theft, tampering, and corruption. Several commenters noted the rise in data breaches and the importance of this objective in keeping health information well secured.

A commenter suggested triggers to remind providers to conduct the security risk assessment. Many commenters supported the requirement that providers conduct a security risk analysis upon installation or upgrade of CEHRT.

Response: We appreciate the support for this measure. As we stated in our proposal, we included administrative and physical safeguards because an entity would require them in addition to technical safeguards to implement security measures to reduce the risks and vulnerabilities identified. Technical safeguards alone are not enough to ensure the confidentiality, integrity, and availability of ePHI.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider’s risk management process.

As noted in the proposed rule, a risk analysis must assess the risks and vulnerabilities to ePHI created or maintained by the CEHRT and must be conducted or reviewed for each EHR reporting period, and any security updates and deficiencies identified should be included in the provider’s risk management process and implemented or corrected as dictated by that process.

To address inquiries about the relationship between this measure and the HIPAA Security Rule, we explained that the requirement of the proposed measure is narrower than what is required to satisfy the security risk analysis requirement under 45 CFR 164.308(a)(1). The requirement of the proposed measure is limited to annually conducting or reviewing a security risk analysis to assess whether the technical, administrative, and physical safeguards and risk management strategies are sufficient to reduce the potential risks and vulnerabilities to the confidentiality, availability, and integrity of ePHI created by or maintained in CEHRT. In contrast, the security risk analysis requirement under 45 CFR 164.308(a)(1) must assess the potential risks and vulnerabilities to the confidentiality, availability, and integrity of all ePHI that an organization creates, receives, maintains, or transmits. This includes ePHI in all forms of electronic media, such as hard drives, floppy disks, CDs, DVDs, smart cards or other storage devices, personal digital assistants, transmission media, or portable electronic media.

In the Stage 3 proposed rule at 80 FR 16746 through 16747, we further proposed that the timing or review of

the security risk analysis to satisfy this proposed measure must be as follows:

- EPs, eligible hospitals, and CAHs must conduct the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition. The initial security risk analysis and testing may occur prior to the beginning of the first EHR reporting period using that Edition of CEHRT.
- In subsequent years, a provider must review the security risk analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and make updates to its analysis as necessary, but at least once per EHR reporting period.

Comment: A commenter suggested that “mandatory consequential insurance” be required of all parties involved in data handling, storage, and dissemination.

Response: We thank the commenter for their suggestion and we will share the suggestion with other programs and agencies, which deal directly with the business requirements established under the HIPAA security rules.

Comment: Several commenters stated that inclusion of this objective was superfluous and redundant, as it is already required by HIPAA. Another suggested that we accept compliance with the HIPAA Security Rule as fulfillment of this objective. A commenter noted that it is confusing when there are requirements from more than one oversight agency. They noted that protecting patient health information is in the purview of the OCR.

Response: We disagree. In fact, in our audits of providers who attested to the requirements of the EHR Incentive Program, this objective and measure are failed more frequently than any other requirement. We have included this objective in all Stages because of the importance of protecting patients’ ePHI. Although OCR does oversee the implementation of the HIPAA Security Rule and the protection of patient health information, we believe it is important and necessary for a provider to attest to the specific actions required to protect ePHI created or maintained by CEHRT in order to meet the EHR Incentive Program requirements.

Comment: Several commenters stated that the proposed measure is “too comprehensive” and would be very difficult, time consuming, and expensive.

Many commenters requested clarification about the requirement to perform a security risk analysis when CEHRT is upgraded or patched. Others noted that requiring a security risk

analysis whenever software is updated is particularly burdensome.

A commenter recommended changing the requirement of “conduct or review a security risk analysis” to “conduct and review a security risk analysis,” to ensure both the behavior and the review of a security risk analysis will be completed. Several commenters requested further clarification of the timing for completion of the security risk assessment.

Response: We disagree with the concept that the objective as proposed is too comprehensive. We believe that the proposed addition of administrative and technical safeguards to this measure enables providers to implement risk management security measures to reduce the risks and vulnerabilities identified. Administrative safeguards (for example, risk analysis, risk management, training, and contingency plans) and physical safeguards (for example, facility access controls, workstation security) are also required to protect against threats and impermissible uses or disclosures to ePHI created or maintained by CEHRT.

The proposed requirement is to perform the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition. Thus, it would be required when a provider upgraded from EHR technology certified to the 2014 Edition to EHR technology certified to the 2015 Edition as established by ONC. We note that the second part of the requirement states a review must be conducted at least on an annual basis, and additional review may be required if additional implementation changes are subsequently made that were not included and planned for in the initial review.

We note that a security risk analysis is not a discrete item in time, but a comprehensive analysis covering the full period of time for which it is applicable; and the annual review of such an analysis is similarly comprehensive. In other words, the analysis and review are not merely episodic but should cover a span of the entire year, including a review planning for future system changes within the year or a review of prior system changes within the year. Therefore, we believe the commenters’ concerns may be a semantic misunderstanding of the nature of an analysis and annual review. We proposed to maintain the previously finalized Stage 2 objective on protecting ePHI, which includes the statement “conduct or review” for both the EHR Incentive Programs in 2015 through 2017 and for Stage 3.

We note that for the proposed objective and measure, the measure must be completed in the same calendar year as the EHR reporting period. If the EHR reporting period is 90 days, it must be completed in the same calendar year. This may occur either before or during the EHR reporting period; or, if it occurs after the EHR reporting period, it must occur before the provider attests or before the end of the calendar year, whichever date comes first. Again, we reiterate that the security risk analysis and review should not be an episodic “snap-shot” in time, but rather include an analysis and review of the protection of ePHI for the full year no matter at what point in time that analysis or review are conducted within the year. In short, the analysis should cover retrospectively from the beginning of the year to the point of the analysis and prospectively from the point of the analysis to the end of the year.

Comment: A commenter noted that the measure only addresses compliance and risk and should also address usability. They suggested that the analysis of security should look at how the data is used and if patients can readily access the data.

Response: We note that other objectives in the EHR Incentive Program, as well as other certification requirements around the technology, include functions related to patient access to health data as well as the sharing of health data with patients and other providers. Inherent in these objectives is the requirement to use certification criteria in the action or process of information sharing. Therefore, these actions and functions are part of the CEHRT and ePHI protections, which should be included in the provider’s security risk analysis and review. We note that providers should employ a security risk analysis that is most appropriate to their own organization, which may include several resources for strategies and methods for securing ePHI. Completing a security risk analysis requires a time investment, and may necessitate the involvement of security, HIT, or system IT staff or support teams at your facility. The OCR provides broad scale guidance on security risk analysis requirements at: <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>.

In addition, other tools and resources are available to assist providers in the process. For example, the ONC provides guidance and an SRA tool created in conjunction with OCR on its Web site at: <http://www.healthit.gov/providers-professionals/security-risk-assessment-tool>.

Comment: Commenters questioned if the SRA Tool is only for providers and professionals in small and medium sized practices asking for further information on the definitions of small, medium, and large practices. Another commenter requested the identification of additional guidance for solo or small group practices.

Several commenters recommended that CMS collaborate with the OCR to develop more robust guidance on conducting security risk assessments and understanding and implementing encryption. A commenter suggested a national education campaign to help ensure that they are adequately equipped to protect ePHI.

Response: We decline to define practice size in this final rule with comment period. Instructions for the SRA tool notes its usefulness to small and medium practices because it was intended to provide support to organizations, which often have more limited staff and organizational knowledge on ePHI than larger organizations. However, the SRA Tool information is applicable to and may be useful for organizations of any size.

In the Stage 3 proposed rule (80 FR 16747), we did note that OCR provides broad scale guidance on security risk analysis requirements and that other tools and resources are available to assist providers in the process. In addition, CMS and ONC will continue to work to provide tools and resources, tip sheets, and to respond to FAQs from providers and developers on the privacy and security requirements.

Comment: A commenter requested clarification of the term “correcting identified security deficiencies” as not all risks can be corrected. Commenters requested information on identity proofing, authentication, and authorization. Another commenter requested more than a passing mention of encryption.

Response: At minimum, providers should be able to show a plan for correcting or mitigating deficiencies and that steps are being taken to implement that plan. Our discussion of this measure as it relates to 45 CFR 164.308(a)(1) is only relevant for purposes of the EHR Incentive Program requirements and is not intended to supersede or satisfy the broader, separate requirements under the HIPAA Security Rule and other rulemaking. For information on identity proofing, authentication, authorization, and encryption, we refer readers to the OCR Web site, www.hhs.gov/ocr.

As noted in the Stage 1 final rule (75 FR 44314 at 44368), while this objective is intended to support compliance with

the HIPAA Privacy and Security Rules, we maintain that meaningful use is not the appropriate regulatory tool to ensure compliance with the HIPAA Privacy and Security Rules. In addition, as noted in the Stage 2 final rule, the scope of the security risk analysis for purposes of this meaningful use measure applies only to data created or maintained by CEHRT and does not apply to data centers that are not part of CEHRT (77 FR 53968 at 54003).

After consideration of the comments received on this objective and measure, we are finalizing the objective as proposed and finalizing the measure with a modification to replace the word "stored" with the phrase "created or maintained." We are adopting this change to correct a discrepancy between the text of the objective and the measure as well as between the measure (the objective reads "created and maintained") and to better reflect the HIPAA security rules. We are finalizing the objective and measure as follows:

Objective 1: Protect Patient Health Information

Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

We are adopting Objective 1: Protect Patient Health Information at § 495.24(d)(1)(i) for EPs and § 495.24(d)(1)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 2: Electronic Prescribing

In the Stage 3 proposed rule (80 FR 16747 through 16749), we proposed to maintain the objective and measure

finalized in the Stage 2 final rule (77 FR 53989 through 53990) for electronic prescribing for EPs, with minor changes. We also proposed to maintain the previous Stage 2 menu objective for eligible hospitals and CAHs as a required objective for Stage 3 with an increased threshold.

Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

We proposed to continue to define "prescription" as the authorization by a provider to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We proposed to continue to generally define a "permissible prescription" as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–V (DEA Web site at <http://www.deadiversion.usdoj.gov/schedules/index.html>) (77 FR 53989), with a slight modification to allow for inclusion of scheduled drugs where such drugs are permitted to be electronically prescribed. We proposed that providers who practice in a state where controlled substances may be electronically prescribed who wish to include these prescriptions in the numerator and denominator may do so under the definition of "permissible prescriptions" for their practice. If a provider chooses to include such prescriptions, they must do so uniformly across all patients and across all allowable schedules for the duration of the EHR reporting period. We proposed to continue to exclude over-the-counter (OTC) medicines from the definition of a prescription, although we encouraged public comments on whether OTC medicines should be included in this objective for Stage 3.

In the Stage 2 final rule at (77 FR 53989), we discussed several different workflow scenarios that are possible when an EP prescribes a drug for a patient and that these differences in transmissions create differences in the need for standards. For Stage 3, we proposed to maintain this policy for Stage 3 for EPs and extend it to eligible hospitals and CAHs so that only a scenario in which a provider (1) Prescribes the drug; (2) transmits it to a pharmacy independent of the provider's organization; and (3) The patient obtains the drug from that pharmacy requires the use of standards to ensure that the transmission meets the goals of electronic prescribing. In that situation, standards can ensure the whole process

functions reliably. In all cases under this objective, the provider needs to use CEHRT as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the provider's organization, such transmission must be pursuant to ONC HIT Certification Program criteria.

Comment: Some commenters recommended that OTC medications should be excluded in the definition of prescription, as they are not typically prescribed electronically.

Response: We thank commenters for their input and agree that OTC medications should continue to be excluded from the definition.

Proposed EP Measure: More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

We proposed to maintain for Stage 3 the exclusion from Stage 2 for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. We also proposed to maintain for Stage 3 the exclusion from Stage 2 if no pharmacies within a 10-mile radius of an EP's practice location at the start of his or her EHR reporting period accept electronic prescriptions (77 FR 53990). This is 10 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. For EPs practicing at multiple locations, they are eligible for the exclusion if any of their practice locations equipped with CEHRT meet this criterion. An EP would not be eligible for this exclusion if he or she is part of an organization that owns or operates its own pharmacy within the 10-mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Threshold: The resulting percentage must be more than 80 percent in order for an EP to meet this measure.

Exclusions: Any EP who: (1) Writes fewer than 100 permissible

prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.

Proposed Eligible Hospital/CAH Measure: More than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

We proposed to limit this measure for Stage 3 to only new and changed prescriptions and invited public comment on whether a hospital would issue refills upon discharge for medications the patient was taking when they arrived at the hospital and, if so, whether distinguishing those refill prescriptions from new or altered prescriptions is unnecessarily burdensome for the hospital.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary and transmitted electronically.

Threshold: The resulting percentage must be more than 25 percent in order for an eligible hospital or CAH to meet this measure.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.

In the proposed rule, we recognized that not every patient will have a formulary that is relevant to him or her. If a relevant formulary is available, then the information can be provided. If there is no formulary for a given patient, the comparison could return a result of formulary unavailable for that patient and medication combination, and the provider may count the prescription in the numerator if they generate and transmit the prescription electronically as required by the measure.

Comment: A few commenters were in support of the e-prescribing objective because it is an important priority in quality reporting efforts.

Response: We appreciate the support and note as we have previously stated, transmitting the prescription

electronically promotes efficiency and patient safety through reduced communication errors.

Comment: Many commenters expressed concerns about requiring e-prescribing for hospitals where the objective was previously a menu option. Some noted that the shift from optional to required, combined with an increased threshold for Stage 3, makes the objective difficult to achieve for eligible hospitals and CAHs.

Response: We thank the commenters for sharing their concerns. However, we believe the potential benefits of electronic prescribing are substantial. As discussed in the Stage 2 final rule (77 FR 53989), transmitting the prescription electronically promotes efficiency and patient safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient, which works in conjunction with clinical decision support interventions enabled at the generation of the prescription. In addition, we note that, as required by the HITECH Act, e-prescribing has been a required part of the EHR Incentive Programs for EPs since 2011. As noted in the Stage 3 proposed rule, eligible hospital and CAH performance on electronic prescribing in 2014 was well over the threshold. We believe that the continued expansion of the infrastructure and 3 years to transition toward incremental increases via the objective in place for 2015 through 2017 will support hospitals in succeeding on this measure.

Comment: Some commenters requested exclusions for eRx because they have less than 100 office visits (in concurrence with previous requirements) or have an average low census. Others simply stated that they could not meet the measure.

Response: We note that we proposed to maintain for Stage 3 the exclusion from Stage 2 for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. We also proposed to maintain for Stage 3 the exclusion from Stage 2 if no pharmacies within a 10-mile radius of an EP's practice location at the start of his or her EHR reporting period accept electronic prescriptions. For eligible hospitals and CAHs in Stage 3, there is an exclusion if they do not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period. We do not agree with setting an exclusion based on office visits, as the

denominator for the measure is based not on office visits but on permissible prescriptions.

Comment: Several commenters stated that the threshold of over 80 percent for EPs is too high. Commenters cited this high threshold as a potential patient safety risk for providers switching products, since systems issues could occur from inappropriately expediting implementation in order to meet the high threshold.

Some of these commenters expressed that if the provider is required to query a drug formulary, the provider cannot be expected to meet the 80 percent threshold. Further commenters discussed the disconnect between the various options for formulary queries and discussed the ongoing evolution of standards specifically referencing the following issues:

- Formulary queries where no formulary exists may generate errors on some systems;
- Formulary queries of formularies with access restrictions, either technological restrictions or proprietary restrictions limit the ability to query even where such a formulary is available;
- Static formularies are often not fully electronic, are not a format that can be queried, or are updated infrequently so they provide limited benefit;
- Real time formulary query standards are split with as many as three primary options available in the industry.

Despite these concerns, many commenters noted that they agree with the concept of an automated, real-time formulary query. Commenters stated that they believe it provides a value for patients when the query is feasible and successful.

Response: As we noted in the proposed rule (80 FR 16747), our analysis of the attestation data indicates the majority of EPs have already been exceeding this threshold; however, we note that each year a small but significant portion of EPs may struggle to meet this measure if they are engaged in a transition from one EHR product to another or in a full upgrade of CEHRT to a new Edition. For many functions, the potential risk to patient safety during these transitions may be easily mitigated; however, because the appropriate management of prescribed medications can be critical for both acute and chronic patient care, the risk for electronic prescribing during transitions may be significant. We are therefore finalizing a threshold of 60 percent rather than the 80 percent proposed. We agree with the provider commenter concerns regarding the drug

formulary query and reiterate that the long-term goal is to move toward real-time automated queries using a unified standard. For the short term, as noted for the electronic prescribing objective and measure for 2015 through 2017 in section II.B.2.a(iv), we believe that the query function should be maintained. However, providers are only required to meet this part of the measure to the extent that such a query is automated by their CEHRT and to the extent that a query is available and can be automatically queried by the provider. This means that if a query using the function of their CEHRT is not possible or shows no result, a provider is not required to conduct any further manual or paper-based action in order to complete the query, and the provider may count the prescription in the numerator.

Comment: Commenters noted that controlled substances should be included where feasible, as the inclusion would reduce the paper based prescription process often used for such prescriptions, as long as the inclusion of these prescriptions were permissible in accordance with state law. Commenters noted that the ability to electronically prescribe controlled substances provides prescribers with a way to manage treatments for patients with pain electronically and also deters creation of fraudulent prescriptions, which is a major concern in combating opioid misuse and abuse.

Response: We agree with commenters that the eventual progression toward universal inclusion of controlled substances in electronic prescribing is a desired goal. However, as stated previously we believe that at present this should remain an option for providers, but not be required. As many states have now have eased some of the prior restrictions on electronically prescribing controlled substances, we believe it is no longer necessary to categorically exclude controlled substances from the term “permissible prescriptions.” Therefore we will define a permissible prescription as all drugs meeting our current definition of a prescription as the authorization by a provider to dispense a drug that would not be dispensed without such authorization and we will no longer distinguishing between prescriptions for controlled substances and all other prescriptions. Instead will refer only to permissible prescriptions consistent with the proposed definition for Stage 3 (80 FR 16747) as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–

V¹² (77 FR 53989) with a modification to allow for inclusion of scheduled drugs where such drugs are permissible to be electronically prescribed. Therefore the continued inclusion of the term “controlled substances” in the denominator may no longer be an accurate description to allow for providers seeking to include these prescriptions in the circumstances where they may be included. We are modifying the denominator to remove this language. Again, we note this is only a change in wording and does not change the substance of our current policy that providers have the option, but are not required, to include prescriptions for controlled substances in the measure for Stage 3. For the EHR Incentive Programs in 2015 through 2017, we note that the inclusion of controlled substances under permissible prescriptions is optional under the Electronic Prescribing Objective (see section II.B.2.a.iv). For Stage 3, while we intended to maintain this option, based on public comment received and the progress of states toward acceptance of electronic prescribing of controlled substances we are modifying this policy that the inclusion of controlled substances should be required where it is feasible to electronically prescribe the drug and where allowable by law. We believe the reduced threshold of 60 percent will help to mitigate the additional effort to meet this requirement and that the benefit outweighs this increased burden.

Therefore, we are changing the measure for this objective to remove the language regarding controlled substances. Instead, we are adopting that under “permissible prescriptions” for the Stage 3 objective providers must may include electronic prescriptions of controlled substances in the measure where creation of an electronic prescription for the medication is feasible using CEHRT and where allowed by law for the duration of the EHR reporting period.

After consideration of the comments received, we are adopting the objective and exclusion for electronic prescribing as proposed. We will continue to define “prescription” as the authorization by a provider to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We are finalizing changes to the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications

can be electronically prescribed. We are finalizing that these prescriptions may be included in the definition of “permissible prescriptions” at the provider’s discretion where allowable by law.

We will not include OTC medicines in the definition of a prescription for this objective. We are maintaining the different workflow scenarios that are possible as discussed in the Stage 2 final rule at (77 FR 53989). We are maintaining this policy for Stage 3 for EPs and extending it to eligible hospitals and CAHs.

For EPs, eligible hospitals and CAHs we are finalizing the objective as follows:

Objective 2: Electronic Prescribing

Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

EP Measure: More than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period.

- *Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

- *Threshold:* The resulting percentage must be more than 60 percent in order for an EP to meet this measure.

- *Exclusions:* Any EP who: (1) writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP’s practice location at the start of his or her EHR reporting period.

Eligible Hospital/CAH Measure: More than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

- *Denominator:* The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.

¹² (DEA Web site at <http://www.deadiversion.usdoj.gov/schedules/index.html>).

- *Numerator*: The number of prescriptions in the denominator generated, queried for a drug formulary and transmitted electronically.

- *Threshold*: The resulting percentage must be more than 25 percent in order for an eligible hospital or CAH to meet this measure.

- *Exclusion*: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.

We are adopting Objective 2: Electronic Prescribing at § 495.24(d)(2)(i) for EPs and § 495.24(d)(2)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 3: Clinical Decision Support

Clinical decision support at the relevant point of care is an area of HIT in which significant evidence exists for substantial positive impact on the quality, safety, and efficiency of care delivery. For Stage 3 of the EHR Incentive Programs, we proposed to maintain the Stage 2 objective with slight modifications and further explanation of the relevant point of care, the types of CDS allowed, and the selection of a CDS applicable to a provider's scope of practice and patient population.

First, we offered further explanation of the concept of the relevant point of care and note that providers should implement the CDS intervention at a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention. Second, many providers may associate CDS with pop-up alerts. However, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow-optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time. These may include but are not limited to: computerized alerts and reminders

for providers and patients; information displays or links; context-aware knowledge retrieval specifications which provide a standard mechanism to incorporate information from online resources (commonly referred to as InfoButtons); clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information. These functionalities may be deployed on a variety of platforms (that is, mobile, cloud-based, installed).¹³ We continue to encourage innovative efforts to use CDS to improve care quality, efficiency, and outcomes. Health IT functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care. CDS is not intended to replace clinician judgment, but rather is a tool to assist care team members in making timely, informed, and higher quality decisions.

Proposed Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

We proposed to retain both measures of the Stage 2 objective for Stage 3 and that these additional options stated previously on the actions, functions, and interventions may constitute CDS for purposes of the EHR Incentive Programs and would meet the measure requirements outlined in the proposed measures.

Comment: Most commenters agreed that clinical decision support should be included as an objective in Stage 3, and many expressed appreciation for the consistency between the existing Stage 2 objective and Stage 3. Some commended CMS' emphasis on clinical decision support tools in the proposed rule. Others were also pleased that CMS is aligning this objective with the HHS National Quality Strategy goals by emphasizing preventive care, chronic condition management, and heart disease and hypertension as areas of focus for quality improvement. A commenter acknowledged the value of CDS available in EHR technology in improving patient safety and care quality, and believes that this requirement has become obsolete as an attestation measure. Others similarly

suggest that this measure is "topped out" because most participants in the Medicare and Medicaid EHR Incentive Program have many more than 5 CDS implemented in their EHRs, but they believed that CDS is a statutory requirement.

Response: We appreciate the support for this objective. As we stated in the proposed rule, clinical decision support at the relevant point of care is an area of health IT in which significant evidence exists for substantial positive impact on the quality, safety, and efficiency of care delivery. We believe these factors outweigh the potential reporting burden in place for providers who have significantly more than 5 CDS interventions in place for whom the measurement may no longer be required.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Measure 1: Implement 5 clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent 4 CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

Where possible, we recommend providers implement CDS interventions that relate to care quality improvement goals and a related outcome measure CQM. However, for specialty hospitals and certain EPs, if there are no CQMs that are outcome measures related to their scope of practice, the provider should implement a CDS intervention related to a CQM process measure; or if none of the available CQMs apply, the provider should apply an intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care.

Comment: Many commenters supported Measure 1 (period), with a significant number supporting CMS for acknowledgement of the wide variety of innovative clinical decision tools that can be used. Some acknowledged "alarm fatigue" and the subsequent ignoring of alerts, so they appreciated the alternatives to pop-up alerts. As an alternative to alerts, one provider suggested that information display as

¹³ FDASIA Health IT report available on the FDA Web site at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

links for condition-specific order sets, diagnostic support, and contextually relevant reference information, which seem to be more user-friendly support tools. A commenter stated that the multiple tools available to meet the requirements of CDS may be difficult and there could be substantial costs associated with the tools.

Other commenters requested clarification of the types of resources that will count towards meeting the requirements of the EHR Incentive Programs related to CDS. Specifically, commenters asked about the InfoButton standard, and the requirement that RCERHT enable users to review the attributes of CDS resources.

Response: Our examples are intended to illustrate that CDS encompasses a variety of workflow-optimized information tools. The examples are meant to be illustrative and not a requirement to utilize all of the options.

We proposed to embrace a broad definition of CDS, including (but not limited to) resources such as: Computerized alerts and reminders for providers and patients, clinical guidelines, condition-specific order sets, documentation templates, focused patient data reports and summaries, and contextually relevant reference information. We posted a tip sheet and guidance on the CMS Web site, www.cms.hhs.gov/ehrincentive, which includes several examples of CDS and information on the general intent of this requirement, and referencing best practices for using CDS to improve care. The guidance also clarifies that CDS need not necessarily be presented during a patient encounter, or be limited to interventions targeted at physicians, and is *not* limited to interruptive alerts or reminders. CDS is often an integrated part of the provider's EHR system, but may also present in a variety of other mechanisms, including but not limited to: pharmacy systems, patients' personal health records (PHRs), or Patient portals provided by the practice.

The InfoButton standard can be used to provide hyperlinks to information, such as clinical guidelines or patient data summaries, at the relevant point in the care continuum and therefore represents one type of CDS that EPs, eligible hospitals, and CAHs may use to meet the EHR Incentive Programs CDS requirements. There are also likely to be cases where it makes sense for a CDS resource to display certain attributes at the time of presentation, or for a resource to include an InfoButton linking to additional information with CDS attributes. The potential workflows and implementations of these resources within a CDS is varied and should be

tailored to best meet the provider's needs. However, please note that in this example, the use of the InfoButton would not count as a separate or additional CDS intervention, but rather would be a supporting part of the one CDS of which it is a part.

Comment: For Measure 1, many commenters appreciated the strengthened connection of CQMs to CDS. However, some commenters recommended removing the requirement to link CDS to CQMs in favor of high-priority safety and quality improvement objectives. A commenter clarified that eliminating the link would enable them to meet their system quality improvement goals and would remove the measurement burden of tracking links between CDS and CQMs. Some commenters noted a lack of CQMs for some provider types and referenced pediatricians. Another stated that if the EHR developer limits the number of CQMs that are included in the CEHRT, it may limit a providers' ability to implement CDS. A commenter inquired about changes to CQMs that could relate to selected CDS. Another recommended that CDS interventions be grandfathered in for a year after a CQM change.

Many commenters requested clarification of "high-priority health conditions." A commenter suggested that "high-priority health conditions" be replaced with "conditions relevant to the EP's scope of practice". Another suggested that the CDS be related to 4 or more CQMs or high-priority health conditions. Yet another commenter stated that the high priority health conditions are not related to many of the specialties, including surgery, pediatrics, or medical subspecialties. They recommended that we allow providers to link to clinical guidelines relevant to their practice or a clinical registry that can provide real-time specialty-specific data on their scope of practice if there are not four relevant CQMs. A commenter urged us to include immunization forecasting as a measure of CDS. Another commenter requested that we consider behavioral health as an additional priority area. A commenter does not believe CDS interventions are applicable to providers servicing elderly patient populations, specifically those in nursing homes with cognitive deficit since their mental functions are limited and life expectancy short.

Response: For providers linking CDS to CQM selections, we proposed that providers are allowed the flexibility to implement CDS interventions that are related to any of the CQMs that are finalized for the EHR Incentive Program. They are not limited to the CQMs they

choose to report and we note that we have a recommended set of CQMs for EPs, which includes both a set for adult population and for pediatric populations, which may serve as a guide.¹⁴ As we stated when we finalized this measure for Stage 2 of the EHR Incentive Programs (77 FR 53996), it is our expectation that, at a minimum, providers will select CDS interventions to drive improvements in the delivery of care for the high-priority health conditions relevant to their patient population. CQMs may be changed on an annual basis through the PFS or IPPS rulemaking. As CQMs are still required as part of a provider's demonstration of meaningful use, providers should modify their CDS selections if CQMs change over time.

Providers who are not able to identify CQMs that apply to their scope of practice or patient population may implement CDS interventions that they believe are related to high-priority health conditions relevant to their patient population and will be effective in improving the quality, safety or efficiency of patient care. These high priority conditions must be determined prior to the start of the EHR reporting period in order to implement the appropriate CDS to allow for improved performance. We proposed to require a minimum number of CDS interventions, and providers must determine whether a greater number of CDS interventions are appropriate for their patient populations.

Comment: A commenter recommended an exclusion for physicians who face challenges implementing 5 CDS interventions. Another requested that only 3 CDS interventions be required. A commenter recommended an exclusion for highly specialized EPs and a reduction in the number of interventions required for each individual EP.

Response: We believe that CDS at the point of care is an area of health IT in which significant evidence exists for its substantial positive impact on the quality, safety, and efficiency of care delivery. Therefore, we did not propose exclusion for this measure. In addition, we proposed to offer considerable flexibility in the selection of the CDS interventions.

Comment: A commenter questioned if all the CDS tools suggested are required. Another commenter recommended that HHS support research that would help

¹⁴ EHR Incentive Programs Recommended Core Set Adult and Pediatric Clinical Quality Measure Tables available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2014_ClinicalQualityMeasures.html.

providers identify the most valuable CDS interventions and the most effective placement of such interventions in provider workflows.

Response: We offered a list of workflow optimized information tools to illustrate some examples in the Stage 3 proposed rule (80 FR 16749). It is not meant to be list of required tools, nor is it an exhaustive list of all the options available. Also in the Stage 3 proposed rule (80 FR 16750), CMS and ONC have provided examples of CDS interventions as well as program models such as Million Hearts, which may offer suggestions to providers and raise awareness of the possibilities available. CMS and ONC will consider providing further guidance as to CDS options, CDS and CQM pairings, and industry research on various CDS implementations.

Comment: A commenter requested a clarification on the relationship between the functions that are included in the definition of CEHRT and the actions that are required for the EHR Incentives Programs. Some commenters expressed concern that EPs and eligible hospitals and CAHs might be limited only to CDS that ONC had certified. Several commenters also expressed concern that the CDS requirements for the EHR Incentive Program objectives do not match the standards for certification and question if the certification requirements for health IT would limit the types or utility of CDS a provider might use to meet the Clinical Decision Support Objective.

Response: CMS does not certify CDS functions or resources, but instead defines that a provider must use CDS resources and that those resources must meet the ONC certification criteria to meet the definition of CEHRT. The EHR Incentive Programs do not otherwise restrict a provider's ability to choose any CDS option or resource to meet their unique needs. For the certification criteria for CDS, the ONC 2015 Edition proposed rule (80 FR 16804 through 16921) proposed the functionalities that health IT developers would build into their "CDS module" to meet the certification criteria. These "CDS modules" are what meet the CEHRT definition for the EHR Incentive Programs. However, while the certification rule specifies that the "CDS module" that is certified to the CDS standard must have certain capabilities to provide or enable CDS for provider use, it does not certify the supports or resources themselves. This means that the ONC health IT certification criteria are designed to ensure that the "CDS module" implemented by EPs and eligible hospitals and CAHs will enable

them to meet the CDS Objective requirements without limiting the potential use and innovation of a wide range of options for providers.

Comment: Several commenters recommended removing the "entire EHR reporting period" from the measure specifications to limit unnecessary measurement burden. Another commenter was concerned that the requirement for CDS interventions to be in place for the entire reporting year would make it impossible for EPs, eligible hospitals, and CAHs to change CEHRT mid-year and remain eligible.

Response: We disagree. We believe that having providers implement improvements in clinical performance for high-priority health conditions will result in improved patient outcomes and believe CDS should be in place for the entire EHR reporting period. We note that we understand reasonable downtime as may be expected with any health IT systems to ensure security or fix any issues which arise is acceptable. We intend for the implementation of 5 five CDS interventions to be a minimum. We do not intend to limit the number of interventions that may be implemented if an organization chooses to implement more than 5 five. The same interventions do not have to be implemented for the entire EHR reporting period as long as the threshold of 5 is maintained for the duration of the EHR reporting period. For example, if a provider identifies quality improvement goals that change the quality improvement and CDS implementation plan over the course of the year, they may make these changes as long as the total number of CDS interventions implemented at any given time during the EHR reporting period is 5 or more. In fact, we expect that EPs, eligible hospitals, and CAHs will regularly update and adjust their portfolios of CDS interventions—fine-tuning them to evolving patient population needs and in response to each intervention's observed impact on the related CQM(s).

Comment: Many commenters were concerned about the documentation required for audit to demonstrate that a specific CDS is implemented for the duration of the reporting period. Another commenter suggested reducing the audit burden while several commenters suggested a clarification be added to reduce the audit burden by only requiring documentation showing the CEHRT has the functionality.

Several commenters requested clarification in the area of audit readiness and guidance related to expectations for the use of specific CDS at the individual level. They requested that we to consider identifying this

objective as an organizational or group objective rather than a specific eligible professional objective and allow the organization's efforts to meet the requirements for each provider practicing in that organization.

Response: We disagree with the suggestion to allow CDS attestations at a group level. While certain CDS may support providers in a wide range of specialties, others may be designed for particular patient populations or specialties and the selection of CQMs may also be related to the priorities for an individual provider. For example, the Million Hearts campaign may provide CDS models for many providers, but may not be relevant for certain specialties. Providers should be selecting and implementing CDS within their practice based on their priorities to promote quality improvement and positive outcomes for patients, not to avoid a potential audit failure. Furthermore, we note that we will provide guidance to the auditors to support their understanding of the wide scope of CDS interventions available to providers.

Comment: Most commenters supported the second measure related to drug-drug and drug-allergy interaction checks. A commenter suggested clarifying that the use of the word "enabled" signifies that the provider is actively using the functionality as opposed to just having the functionality available. Another appreciated the inclusion of this measure because it is a huge benefit to patient care.

However, a commenter recommended that we allow exclusions from the drug-drug and drug-allergy interaction checks if the EP is a low-volume prescriber.

Response: We appreciate the support for this measure. We meant by "enabled" that the provider should be actively using the function for the duration of the EHR reporting period at the relevant point in care. For the second measure, we did propose an exclusion for any EP who writes fewer than 100 medication orders during the EHR reporting period.

Comment: Several commenters stated that for the second measure they believe it is burdensome to require eligible hospitals, CAHs, and EPs to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Response: We believe that this measure is an important component of the EHR Incentive Programs and offers the opportunity for positive impact on quality, efficiency of care delivery, and especially patient safety. We believe that the functionality for drug-drug and drug-allergy interaction checks should

be enabled and implemented for the duration of the EHR reporting period with the exception of limited unavoidable downtime if a system issue should arise.

After consideration of the public comments received, we are finalizing the objective, measures and exclusion as proposed for EPs, eligible hospitals and CAHs as follows:

Objective 3: Clinical Decision Support

Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

Measure 1: Implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

We are adopting Objective 3: Clinical Decision Support at § 495.24(d)(3)(i) for EPs and § 495.24(d)(3)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 4: Computerized Provider Order Entry

In the Stage 2 final rule, we expanded the use of computerized provider order entry (CPOE) from the Stage 1 objective requiring only medication orders to be entered using CPOE to include laboratory orders and radiology orders. For a full discussion of this expansion, we direct readers to (77 FR 53985 through 53989). We maintain CPOE continues to represent an opportunity for providers to leverage technology to capture these orders to reduce error and maximize efficiencies within their practice, therefore we proposed to maintain the use of CPOE for these

orders as an objective of meaningful use for Stage 3.

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

We proposed to continue our policy from the Stage 2 final rule that the orders to be included in this objective are medication, laboratory, and radiology orders. However, we proposed to expand the third measure of the objective to include diagnostic imaging. This change was intended to address the needs of specialists and allow for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.

For Stage 3, we proposed to continue our policy from the Stage 2 final rule that the orders to be included in this objective are medication, laboratory, and radiology orders as such orders are commonly included in CPOE implementation and offer opportunity to maximize efficiencies for providers. However, for Stage 3, we proposed to expand the objective to include diagnostic imaging, which is a broader category including other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. This change addressed the needs of specialists and allowed for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.

We further proposed to continue the policy from the Stage 2 final rule at 77 FR 53986 that orders entered by any licensed healthcare professional or credentialed medical assistant would count toward this objective. A credentialed medical assistant may enter orders if they are credentialed to perform the duties of a medical assistant by a credentialing body other than the employer. If a staff member of the eligible provider is appropriately credentialed and performs assistive services similar to a medical assistant, but carries a more specific title due to either specialization of their duties or to the specialty of the medical professional they assist, orders entered by that staff member would be included in this objective. We further noted that medical staff whose organizational or job title, or the title of their credential, is other than medical assistant may enter orders if

these staff are credentialed to perform the equivalent duties of a credentialed medical assistant by a credentialing body other than their employer and perform such duties as part of their organizational or job title. We deferred to the provider's discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE. This determination must be made by the EP or representative of the eligible hospital or CAH based on—

- Organizational workflows;
- Appropriate credentialing of the staff member by an organization other than the employing organization;
- Analysis of duties performed by the staff member in question; and
- Compliance with all applicable federal, state, and local laws and professional guidelines.

However, as stated in the Stage 2 final rule at 77 FR 53986, it is apparent that the prevalent time when CDS interventions are presented is when the order is entered into CEHRT, and that not all EHRs also present CDS when the order is authorized (assuming such a multiple step ordering process is in place). This means that the person entering the order would be required to enter the order correctly, evaluate a CDS intervention either using their own judgment or through accurate relay of the information to the ordering provider, and then either make a change to the order based on the information provided by the CDS intervention or bypass the intervention. The execution of this role represents a significant impact on patient safety; therefore, we continued to maintain for Stage 3 that a layperson is not qualified to perform these tasks. We believe that the order must be entered by a qualified individual. We further proposed that if the individual entering the orders is not the licensed healthcare professional, the order must be entered with the direct supervision or active engagement of a licensed healthcare professional.

We proposed to maintain for Stage 3 our existing policy for Stages 1 and 2 that the CPOE function should be used the first time the order becomes part of the patient's medical record and before any action can be taken on the order. The numerator of this objective also includes orders entered using CPOE initially when the patient record became part of the CEHRT, but does not include paper orders entered initially into the patient record or orders entered into technology not compliant with the CEHRT definition and then transferred into the CEHRT at a later time.

In addition, we proposed to maintain for Stage 3 that “protocol” or “standing” orders may but are not required to be excluded from this objective.

We proposed to maintain the Stage 2 description of “laboratory services” as any service provided by a laboratory that could not be provided by a non-laboratory for the CPOE objective for Stage 3 (77 FR 53984). We also proposed to maintain for Stage 3 the Stage 2 description of “radiologic services” as any imaging service that uses electronic product radiation (77 FR 53986). Even though we proposed to expand the CPOE objective from radiology orders to all diagnostic imaging orders, this description would still apply for radiology services within the expanded objective.

We received public comment on our proposals and our response follows.

Comment: The majority of commenters supported the inclusion of this objective. Some of the commenters appreciated the consistency with the previous Stage 2 objective. A commenter requested that we clarify that there are no changes to the objective or to the definition of terms except for “diagnostic imaging.”

Response: We appreciate the support for the objective. We proposed to maintain the Stage 2 CPOE policies except that the third measure would be expanded from radiology orders to diagnostic imaging orders and the thresholds for the measures would be increased.

Comment: Commenters requested clarification of “medical staff member credentialed to perform the equivalent duties of a credentialed medical assistant” and requested clarification on a number of potential roles including an in-house phlebotomist, an ophthalmological assistant, a medical student in residency, and other health care professionals. Other commenters requested clarification on the phrase “under the direct supervision or active engagement of a licensed healthcare professional.”

Response: As noted in the Stage 3 proposed rule (80 FR 16751), we require that the person entering the orders be a licensed health care professional or credentialed medical assistant (or staff member credentialed to the equivalency and performing the duties equivalent to a medical assistant). We defer to the provider’s discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE.

However, the descriptive phrase “direct supervision or active

engagement” was not meant to capture a hierarchical organizational or contractual arrangement, but rather to signify that any required assistance and direction to assess and act upon a CDS and ensure the order is accurately entered should be provided in real time.

Comment: A commenter disagreed that only “certified” medical assistants are capable of entering orders and requested clarification on the specific certification required. Another commenter stated that in Massachusetts, medical assistants are not required to be credentialed in order to practice and there is no local credentialing body for medical assistants. The commenter suggested that if a standard for medical assistant CPOE is required, then the standard should be that the medical assistant must be appropriately trained for CEHRT use (including CPOE) by the employer or CEHRT vendor in order to be counted.

Response: We thank the commenter for their feedback and suggestion. We believe there may be some confusion related to the term “Certified Medical Assistant” which is not used by CMS in our proposed rules or guidance with reference to the credentialed medical assistant or the credentialed medical staff equivalent of a medical assistant. We reiterate that CMS does not require any specific or general “certification” and note that credentialing may take many forms including, but not limited to, the appropriate degree from a health training and education program from which the medical staff matriculated.

We note that a simple search online returns dozens of medical assistant training and credentialing programs as well as local industry associations for Medical Assistants offering resources on training in the Commonwealth of Massachusetts. We note that any such program which met a provider’s requirements for their practice would also be an example of an acceptable credentialing for the purposes of this objective.

We disagree that the training on the use of CEHRT is adequate for the purposes of entering an order under CPOE and executing any relevant action related to a CDS. We believe CPOE and CDS duties should be considered clinical in nature, not clerical. Therefore, CPOE and CDS duties, as noted, should be viewed in the same category as any other clinical task, which may only be performed by a qualified medical or clinical staff.

Proposed Measures: An EP, eligible hospital or CAH must meet all three measures.

Proposed Measure 1: More than 80 percent of medication orders created by

the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

Proposed Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

Proposed Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

We proposed to continue a separate percentage threshold for all three types of orders: Medication, laboratory, and diagnostic imaging. We continue to believe that an aggregate denominator cannot best capture differentiated performance on the individual order types within the objective, and therefore maintain a separate denominator for each order type. We proposed to retain exclusionary criteria from Stage 2 for those EPs who so infrequently issue an order type specified by the measures (write fewer than 100 of the type of order), that it is not practical to implement CPOE for that order type.

We proposed to retain exclusionary criteria from Stage 2 for those EPs who so infrequently issue an order type specified by the measures (write fewer than 100 of the type of order), that it is not practical to implement CPOE for that order type.

Finally, we sought public comment on whether to continue to allow, but not require, providers to limit the measure of this objective to those patients whose records are maintained using CEHRT.

Comment: A few commenters supported not requiring providers to limit the measure of this objective to patients whose records are maintained using CEHRT.

Response: We believe that the majority of providers will store their patient records in CEHRT by the beginning of Stage 3. However, as noted previously, a certain percentage of charts may still be maintained outside of CEHRT (such as workers compensation or other special contracts).

After consideration of public comments received, we maintain the distinction between measures that include only those patients whose records are maintained using CEHRT

and measures that include all patients. Providers may continue to limit the denominator to those patients whose records are maintained using CEHRT for measures with a denominator other than unique patients seen by the EP during the EHR reporting period or unique patients admitted to the eligible hospital or CAH inpatient or emergency department during the EHR reporting period.

Proposed Measure 1: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 medication orders during the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

Proposed Measure 3: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of diagnostic imaging orders created by the EP or authorized providers in the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

We further sought public comment on if there are circumstances which might

warrant an additional exclusion for an EP, such as a situation representing a barrier to successfully implementing the technology required to meet the objective. We also sought comment on if there are circumstances where an eligible hospital or CAH, which focuses on a particular patient population or specialty, may have an EHR reporting period where the calculation results in a zero denominator for one of the measures, how often such circumstances might occur, and whether an exclusion would be appropriate.

Comment: A few commenters noted potential barriers for cost of a system if the provider conducts very few orders of a specific type. Many providers noted they believe that CPOE saves money and delivers process improvement benefits in a relatively short and easily measurable cycle and so saw a strong benefit from the objective.

Many commenters noted that the change from radiology orders to diagnostic imaging orders increases relevance for specialty hospitals. A few commenters requested clarification around the inclusion of diagnostic imaging and how this is different from Stage 2.

Some commenters stated that the increase in thresholds, especially for laboratory and radiology orders, were appropriate and they would be able to meet them. Some commenters supported the increased thresholds noting that our inclusion of this objective provided additional pressure on their organization to work toward a higher goal and maximize the potential benefits CPOE offers. However, some commenters noted that the 80 percent threshold could present a problem for providers who are transitioning between certified EHR technologies within a reporting period. These commenters noted that for CPOE medication orders, and the related CDS interventions for drug-drug and medication-allergies, it is extremely important to allow adequate time for product and process implementation to ensure patient safety and minimize the risk of serious adverse events.

Response: In relation to the potential costs associated, we believe the proposed exclusions would allow providers with significantly low numbers of a certain type or types of orders to exclude the related measure and therefore avoid any unnecessary expenditure. We believe CPOE continues to represent an opportunity for providers to leverage technology to capture these orders to reduce error and maximize efficiencies within their practice.

We appreciate the support for the inclusion of diagnostic imaging for measure 3. We proposed the expansion for diagnostic imaging to include other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology orders which were the limit of the scope of the Stage 2 objective at 80 FR 16750. We believe this change addresses the needs of specialists and allows for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement, benchmarking, and process improvement initiatives within healthcare organizations.

Finally, we thank those commenters who supported the increased thresholds for Stage 3. We have reconsidered the increase for the medication orders measure and are in agreement with commenters who suggested this potential measure should not be raised to this level in order to avoid inadvertently encouraging rushed implementation if a provider is switching between products or implementing an upgrade to the technology. As we explained in our discussion regarding the threshold of the Electronic Prescribing Objective for Stage 3, we believe the appropriate management of medications can be critical for both acute and chronic patient care, and therefore the risk associated with CPOE for medication orders during transitions may be significant. Therefore we will maintain the Stage 2 threshold for that measure only which also aligns the three measures at the same level.

After consideration of the public comments received, at we are finalizing the objective and the measures for CPOE for laboratory orders and CPOE for diagnostic imaging orders and the exclusions for all measures as proposed. We are finalizing the measure for CPOE for medication orders with a modified threshold. We are adopting the objective for EPs, eligible hospitals and CAHs as follows:

Objective 4: Computerized Provider Order Entry

Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

Measure 1: More than 60 percent of medication orders created by the EP or

authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

- *Denominator:* Number of medication orders created by the EP or authorized providers in the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of orders in the denominator recorded using CPOE.

- *Threshold:* The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- *Exclusion:* Any EP who writes fewer than 100 medication orders during the EHR reporting period.

Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

- *Denominator:* Number of laboratory orders created by the EP or authorized providers in the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of orders in the denominator recorded using CPOE.

- *Threshold:* The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- *Exclusion:* Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Denominator:* Number of diagnostic imaging orders created by the EP or authorized providers in the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of orders in the denominator recorded using CPOE.

- *Threshold:* The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- *Exclusion:* Any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

We are adopting Objective 4: Computerized Provider Order Entry at § 495.24(d)(4)(i) for EPs and § 495.24(d)(4)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 5: Patient Electronic Access to Health Information

In the Stage 3 proposed rule (80 FR 16752), we identified two related policy goals within the overall larger goal of improved patient access to health information and patient-centered communication. The first is to ensure patients have timely access to their full health record and related important health information; and that the second is to engage in patient-centered communication for care planning and care coordination. While these two goals are intricately linked, we noted that we see them as two distinct priorities requiring different foci and measures of success. For the first goal, we proposed to incorporate the Stage 2 objectives related to providing patients with access to health information, including the objective for providing access for patients (or their authorized representatives) to view online, download, and transmit their health information and the objective for patient-specific education resources, into a new Stage 3 objective entitled, “Patient Electronic Access” (Objective 5), focused on using CEHRT to support increasing patient access to important health information. For the second goal, we proposed an objective entitled Coordination of Care through Patient Engagement (Objective 6) incorporating the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the ability for patients (or their authorized representatives) to view online, download, and transmit their health information using the functionality of the CEHRT.

In the Stage 3 Patient Electronic Access Objective, we proposed to incorporate certain measures and objectives from Stage 2 into a single objective focused on providing patients with timely access to information related to their care. We also proposed to no longer require or allow paper-based methods to be included in the measures (80 FR 16753) and to expand

the options through which providers may engage with patients under the EHR Incentive Programs. Specifically, we proposed an additional functionality, known as application programming interfaces (APIs), which would allow providers to enable new functionalities to support data access and patient exchange.

We sought comment on what additional requirements might be needed to ensure that for the API— (1) the functionality supports a patient’s right to have his or her protected health information sent directly to a third party designated by the patient; and (2) patients have at least the same access to and use of their health information that they have under the view, download, and transmit option.

Proposed Objective: The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

We continue to believe that patient access to their electronic health information, and to important information about their care, is a high priority for the EHR Incentive Programs.

We noted that for this objective, the provider is only required to provide access to the information through these means; the patient is not required to take action in order for the provider to meet this objective. We also stated that to “provide access” means that the patient has all the tools and information they need to gain access to their health information including, but not limited to, any necessary instructions, user identification information, or the steps required to access their information if they have previously elected to “opt-out” of electronic access. If this information is provided to the patient in a clear and actionable manner, the provider may count the patient for this objective. We further stated that providers may withhold from online disclosure any information either prohibited by federal, state, or local laws or if such information provided through online means may result in significant harm.

Further, we noted that this objective is a requirement for meaningful use and it does not affect an individual’s right under HIPAA to access his or her health information. Providers must continue to comply with all applicable requirements under the HIPAA Privacy Rule, including the access provisions of 45 CFR 164.524.

We received the following comments and our response follows:

Comment: We received a number of comments requesting further clarification of the proposal to incorporate API functionality into an objective for patient electronic access. We received comments requesting clarification around how we envision the relationship between an API and the existing view, download, and transmit functionalities as well how a patient or provider might leverage an enabled API over multiple use cases. Commenters also requested clarification on if the API would replace their patient portal or be a part of it or an additional Web site. Some commenters expressed concern about supporting a second patient portal.

Response: We thank the commenters and offer the following explanation of our intent for the use of an API within the patient electronic access objective as one of the potential functions through which a patient may obtain access to their health information.

First, we do not consider the API to be a “second” patient portal and that the current trend to use a patient portal to meet the view, download and transmit functions, while prevalent and acceptable, is not the only way a provider might meet the current objective. We recognize the value in these systems and support the implementation of patient portals to allow patients to engage with their health care providers for both clinical and administrative information.

However, at a basic level, the EHR Incentive Program currently requires only that providers give their patients access to their health information to be able to do three activities: View their information, download their information, and transmit their information. This is a nuanced but important distinction between the existing Stage 2 requirement and the current systems, which are used to meet it. This distinction is important, as not only do we not require a “patient portal” format for VDT, we also do not advocate such a limit on innovation in software or systems designed to allow patients to access and engage with their health information. We believe that the efficacy of the health IT environment now and the potential for future innovation, relies on the establishment of clear standards and functionality requirements paired with the flexibility to develop differentiated technical specifications, functions, and user interface design that meet those requirements.

This proposed Stage 3 objective for Patient Electronic Access is not a “patient portal” versus “API” requirement or a requirement to support

two patient portals. Instead, this proposed objective is supporting four basic actions that a patient should be able to take:

- View their health information;
- Download their health information;
- Transmit their health information to a third party; and
- Access their health information through an API.

We also believe that these actions may be supported by a wide range of system solutions, which may overlap in terms of the software function used to do an action or multiple actions. This intent to allow for innovation and change within the scope of health IT development is part of a broader goal to lay the foundation for health care systems to support the patient and provider.

An API is a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than is often found in many current “patient portals.”

From the provider perspective, an API could complement a specific provider “branded” patient portal or could also potentially make one unnecessary if patients were able to use software applications designed to interact with an API that could support their ability to view, download, and transmit their health information to a third party.

From the patient perspective, an API enabled by a provider will empower the patient to receive information from their provider in the manner that is most valuable to the patient. Patients could collect their health information from multiple providers and potentially incorporate all of their health information into a single portal, application, program, or other software. Such a solution may be offered on a state, local, or regional basis, for instance, through a health information exchange, or through another commercial vendor. In addition, we recognize that a large number of patients consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make decisions. For this reason, we proposed the inclusion of patient-authorized representatives within the measures.

Comment: Commenters requested clarification on the function of the API itself, the standards in place, the potential process for determining the possible applications, which may leverage the API, and how to successfully provide patients access to their information through an API.

Response: For the provider to implement an API under our proposal, the provider would need to fully enable the API functionality such that any application chosen by a patient would enable the patient to gain access to their individual health information provided that the application is configured to meet the technical specifications of the API. Providers may not prohibit patients from using any application, including third-party applications, which meet the technical specifications of the API, including the security requirements of the API. Providers are expected to provide patients with detailed instructions on how to authenticate their access through the API and provide the patient with supplemental information on available applications that leverage the API. We believe there are multiple paths by which a provider organization may provide this information to the patient, just as the current information for access is provided through a variety of means depending on the circumstances.

Additionally, similar to how providers support patient access to VDT capabilities, we expect that providers will continue to have identity verification processes to ensure that a patient using an application, which is leveraging the API, is provided access to their health information.

We proposed for the Patient Electronic Access objective to allow providers to enable API functionality in accordance with the proposed ONC requirements in the 2015 Edition proposed rule. The certification criteria proposed by ONC would establish API criteria, which would allow patients, through an application of their choice (including third-party applications), to pull certain components of their unique health data directly from the provider’s CEHRT. This could also potentially allow a patient to pull such information from multiple providers engaged in their care. For further discussion on the technical requirements for APIs, we direct readers to the 2015 Edition proposed rule (80 FR 16840 through 16850).

Comment: A number of commenters expressed concern over the privacy and security of patient information through the use of an API. Commenters noted a number of issues including—(1) How the application would or would not be governed by HIPAA; (2) what verification mechanisms would be required to be included by the provider, the EHR system, and the patient in order to allow the enabled API to function with the patient selected application; (3) what standards would be required for the API, the application, and any

provider verification process for enrolling patients; and (4) general concern over the security of having an enabled API for an EHR.

Response: It is recognized that APIs and VDT provide access to sensitive health care material and security and privacy of patients' ePHI is of utmost importance. As has been seen in other industries where system interoperability has enabled considerable benefits for the consumer, security technology is constantly evolving to meet the changing environment. Thus, detailed monitoring, penetration testing, audits, and key management are all necessities. In addition, this changing environment requires similarly nimble guidelines and standards for privacy and security protocols. The EHR Incentive Program includes an Objective to Protect Patient Health Information (see also section II.B.2.b.1 of this final rule with comment period). This objective includes a measure requiring providers to conduct or review a security risk analysis in accordance with HIPAA requirements to ensure the protection of patient ePHI created or maintained by CEHRT. This requirement to conduct and review a security risk analysis would include the certified API enabled as a part of the provider's CEHRT. This analysis must also be done in compliance with HIPAA Security Rules, which would likewise be applicable to the provider actions related to the provision of access to the patient's health information. Beyond this baseline, we believe that evidence in similar technological transitions illustrates the need for a balanced and responsive approach to privacy and security. As noted previously, we encourage providers to innovate around enrollment structures for patients to provide accountability for privacy and security standards; we encourage developers to incorporate security best practices in their design; and we encourage patients to employ sound practices just as they would with their online banking or other online activities regarding personal information.

Comment: Many commenters expressed concerns about successfully meeting the objective because their patient population is elderly, ill, low-income, and/or located in remote, rural areas. These patients do not have access to computers, Internet and/or email and are concerned with having their health information online. A commenter specifically requested that clinics with high elderly populations, especially those in rural areas, be exempt from meeting these patient electronic access requirements. Another commenter

recommended keeping the VDT threshold to Stage 2 levels.

Several comments also included concerns about patients not using or accessing patient portals, which make it difficult for providers and hospitals to meet patient electronic access requirements. Eligible providers and hospitals do not want to be penalized if patients choose not to use the patient portal or send them secure messages. A commenter recommended that compliance with access occur when the patient has been given documentation on how to sign up for the patient portal, and that a patient's decision to opt-out be counted as compliance. The same commenter also recommended that the denominator for compliance with the portal usage measure be counted as the total number of patients in the portal, not the total number of qualified patients discharged in that period.

Many commenters supported the inclusion of patient-authorized representatives within this objective noting that this change is essential for patient care and provides greater flexibility for providers. These commenters noted specific patient populations, such as disabled persons, elderly patients, and newborn patients or young children where the more comprehensive inclusion of non-physician caregivers, family members, and other patient-authorized representatives within the measure more accurately captures the inclusiveness of these interactions and the role that health IT can provide in supporting communications with patients and their caregivers.

Response: We note that this proposed objective is entirely focused on the provision of access to patients or their authorized representatives and does not require the provider to be accountable for the patient using that access. Additionally, the numerator is calculated based on the provision of access by the provider, not based on whether a patient possesses or can obtain technology for their own use. The provision of access by the provider is the entirety of the measurement and any subsequent barriers to access which are outside the providers control do not affect the numerator calculation. In other words, for this measure the provider must ensure the patient has been provided the information they would need to gain access whether or not the patient has the technology they need to gain access.

We believe that the overall focus of this objective on the provision of access allows providers the flexibility to work with patients with a wide range of backgrounds and IT adoption. We

further believe that it prevents any negative unintended consequences of assumptions which may be placed on patients to use or not use various technologies. We believe that no patient should be excluded from access to their health care information for any reason, especially reasons which would allow for a blanket exclusion of any patient based on a demographic factor. We note that we proposed to maintain our current policy, which applies to the Stage 2 Patient Electronic Access Objective, which requires that access be provided, even for those who choose to opt-out via providing them the information and resources they would need to opt back in. We further thank those commenters for their support of the expansion of the concept of access for patient-authorized representatives and note that this inclusion is designed to recognize the existing relationships and expand the access to information for family members and other caregivers who may serve as patient-authorized representatives. Patient-authorized representatives encompass both "personal representatives" as defined by HIPAA, as well as those authorized or designated by an individual.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

We proposed that for measure 1, the patient must be able to access this information on demand, such as through a patient portal, personal health record (PHR), or API and have everything necessary to access the information even if they opt out. We proposed that all three functionalities (view, download, and transmit) or an API must be present and accessible to meet the measure. We further proposed that the functionality must support a patient's right to have his or her protected health information sent directly to a third party designated by the patient consistent with the provision of access requirements at 45 CFR

164.524(c) of the HIPAA Privacy Rule. However, we proposed that if the provider can demonstrate that at least one application that leverages the API is available (preferably at no cost to the patient) and that more than 80 percent of all unique patients have been provided instructions on how to access the information; the provider need not create, purchase, or implement redundant software to enable view, download, and transmit capability independently of the API.

To calculate the percentage, CMS and ONC worked together to define the following for the proposed measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who are provided access to information within 24 hours of its availability to the EP or eligible hospital/CAH.

Threshold: The resulting percentage must be more than 80 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Proposed Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC worked together to define the following for this measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an

eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT.

Threshold: The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We proposed that both measures for this objective must be met using CEHRT.

Comment: A number of commenters expressed concern about the timeframe of 24 hours for the availability, stating that it was either too long for patients to wait or too short a time for providers to adequately review the information provided for accuracy and compliance with any concerns over disclosure of information, such as sensitive test results, mental health issues, or information which must be withheld in order to comply with state or local law.

Response: We appreciate this assessment and recognize that such a review may be required in certain cases where the disclosure or non-disclosure cannot simply be automated. We recognize that provider's workflows, especially for EPs in small practices, may be impacted in these instances where such a need arises. Therefore, we are instead finalizing that information must be included for access within 48 hours for EPs and are retaining the current 36 hours for eligible hospitals and CAHs. We note that this would allow for immediate availability for most patients where the provision of information can be automated and will provide adequate time for review processes for sensitive information by providers as necessary.

Comment: A number of commenters expressed skepticism about the maturity

and security of API technology for patient electronic access, and noted that the ONC API certification process is not fully functional yet. In response to our request for comment regarding expansion of the patient engagement measures to include the use of application programming interfaces (APIs) in addition to, or in place of, a patient portal, one commenter referenced the JASON report and the Argonaut Project¹⁵ and expressed strong support the use of APIs to enhance interoperability, increase patient engagement, and ease the burden of EHR end users with respect to programming, updating, and maintenance. Some commenters expressed concern about the potential cost associated with API implementation.

Response: As noted, referencing the JASON report and Argonaut Project, the use of APIs in the health care industry represents an opportunity for both patients and providers to leverage technology to support the free flow of information in a dynamic and secure manner. This technology is already in widespread use in other industries with similar implementation challenges, such as finance, and the social IT environment includes the use of APIs in simple every day interactions. Some low-cost and even free API functions already exist in the health IT industry, and we expect third-party application developers to continue to create low-cost solutions that leverage APIs as part of their business models.

Further, we encourage health IT system developers to leverage the existing API platforms and applications as this would allow developers to immediately begin offering providers no-cost, or low-cost solutions to implement and enable an API as part of their current systems even prior to the implementation of Stage 3 in 2018.

In terms of cost, as we have stated in the past with the view, download, and transmit functions, we do not believe it would be appropriate for EPs and hospitals or CAHs to charge patients a fee for accessing their information using an API or VDT. We believe the economies of scale provided by enabling an API render the cost of use by an individual patient minimal and we do not believe that providing free access to patients represents a burden to the provider.

However, we recognize that the potential usage of APIs extends beyond

¹⁵ JASON Report: http://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf Argonaut Project: <http://hl7.org/implement/standards/fhir/2015Jan/argonauts.html>.

the individual patient to other provider organizations, non-physician care settings, home health care, and many other uses. We recognize that under very high usage, it may be expensive to support APIs, and in those circumstances, providers may want to consider the feasibility of cost sharing arrangements with outside organizations or businesses, which frequently leverage the enabled API to support care coordination.

Comment: A few comments focused on Measure 2, the requirement to provide CEHRT-generated patient educational materials to patients. A commenter discussed how low patient adoption of portals/APIs makes it difficult to provide more than 35 percent of patients with electronic educational materials. Another commenter requested that—(1) the denominator be patients who have office visits rather than patients who are seen by an EP; and (2) providers who have less than 100 office visits during the EHR reporting period be excluded. Lastly, a commenter opposed only using CEHRT-generated patient educational materials and thought additional materials printed in-office by providers should be acceptable.

Response: We disagree that this measure threshold should be reduced or limited to office visits or that providers should be required or allowed to continue to count paper-based actions toward this measure. We believe that the provision of access to patient-specific education following a similar model as the provision of access to a patient's record will allow providers the opportunity to leverage a wide range of resources for patients and include this information in concert with the patient's electronic health record. We believe that as the technology continues to evolve providers will perform well beyond the threshold and expect that innovative options will progress apace with this progress. We by no means intend to discourage providers from also using paper-based or other methods of providing patients with education about their health and their care. We are simply no longer requiring or allowing paper-based actions to be counted because the EHR Incentive Programs focuses on leveraging health IT to support patient engagement.

We are therefore finalizing Measure 2 as proposed for the method of delivery and with a modification to specify that for the numerator of for measure 2 for each year, the action must occur within the same calendar year as the EHR reporting period, but may occur before, during, or after the EHR reporting period if the EHR reporting period for

the provider is less than a full calendar year. We note that the action must occur prior to the provider submitting their attestation if they attest prior to the end of the calendar year. For measure 1, we refer readers to the discussion on the Alternate Proposals for the measure immediately following.

Alternate Proposals:

For measure 1, we sought comment on the following set of alternate proposals for providers to meet the measure using the functions of CEHRT outlined previously in this section. These alternate proposals involve the requirements to use a view, download, and transmit function or an API to provide patients access to their health information. Measure 1 as proposed would allow providers the option either to give patients access to the view, download, and transmit functionality, or to give patients access to an API. Specifically, we sought comment on whether the API option should be required rather than optional for providers, and if so, should providers also be required to offer the view, download, and transmit function.

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or the patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

Alternate A: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or the patient-authorized representative) is provided access to view online, download, and transmit his or her health information within 24 hours of its availability to the provider; and

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate B: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or

CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; and the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information within 24 hours of its availability to the provider; or,

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate C: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

We welcomed public comment on these proposals. We received the following comments and our response follows:

Comment: The majority of commenters who discussed APIs recommended that the use of APIs be optional (for example, no requirement for both APIs and patient portals); most opposed making APIs mandatory. A few comments specifically noted that patient portals are already in place and it would be counterproductive and financially wasteful to force investment in APIs. Others also expressed skepticism about the maturity and security of API technology for patient electronic access, and noted that the ONC API certification process is not fully functional yet. Commenters noted that EPs, eligible hospitals, and CAHs have worked very hard to establish patient portals, and have encouraged patients to use them and that this effort has required an extraordinary effort in time and financial commitment. The commenters further stated that it would not make financial, strategic, or technical sense to abandon patient portals. They also stated that many patients who have begun to engage with their health record would not be willing to change their approach to obtaining their patient data, and while they may

eventually eagerly accept and use alternatives, it will take time to transition them. Commenters requested maximum flexibility for this measure, noting that the stated goal of providing such flexibility means that the best alternative is to allow providers to choose whether to have a portal or an API, or both, but not to require both. Requiring APIs as a substitute for patient portals represents an overhaul of existing, expensive, and time-consuming technology. CMS should not require such an overhaul.

Response: As noted previously, we disagree that the API functionality cannot be implemented successfully by 2018 as the technology is already in widespread use in other industries and API functions already exist in the health IT industry. Within the Objective for Patient Electronic Access, we see the potential and need for multiple use cases, which leverage a wide range of systems design, from the traditional patient portal to leveraged APIs, which allow providers and patients to expand information sharing among systems. Examples of these use cases could include a patient with a chronic condition seeking to combine records from multiple providers, home health care providers accessing records from multiple patients in real time, patients accessing a wide range of health information and scheduling appointments with or requesting refills from a single provider on a dedicated site, and many more. While we understand the commenters' concern about adding new technology in light of the investment already made in existing technology, we believe that patient access should not be limited to a single function, action or use case when multiple viable options are available to support a wider range of potential use. We believe that the investments that have been made in existing patient portals—serve a positive and necessary function, and those who invested in such portals should not abandon that investment. In addition, as noted previously, we believe that there are existing API options that can be leveraged to provide low-cost health IT solutions that diversify the technology pathways and expand the capacity of providers and patients to share health information. We believe these functions are compatible and complementary of each other and that the appropriate requirement is the inclusion of both concepts by supporting, all four possible actions for patients access (that is, view, download, transmit, and access data through an API).

After consideration of public comments received, we are finalizing

the objective with a modification based on the change to the 24 hour requirement proposed as well as to better represent the functions of CEHRT use. For Measure 1 we are finalizing Alternate A which includes the requirement that providers offer all four functionalities (view, download, transmit, and access through API) to their patients. We further specify that any patient health information must be made available to the patient within 48 hours of its availability to the provider for an EP and 36 hours of its availability to the provider for an eligible hospital or CAH. For measure two, we are finalizing measure a modification to the numerator to specify the timing of the action in relation to the EHR reporting period.

Objective 5: Patient Electronic Access to Health Information

Objective: The EP, eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(2) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

- *Denominator:* The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of patients in the denominator (or patient-authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the provider's CEHRT.

- *Threshold:* The resulting percentage must be more than 80 percent in order for a provider to meet this measure.

Measure 2: The EP, eligible hospital or CAH must use clinically relevant

information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Denominator:* The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the EHR reporting period.

- *Threshold:* The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: A provider may exclude the measures if one of the following apply:

- An EP may exclude from the measure if they have no office visits during the EHR reporting period.

- Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We are adopting Objective 5: Patient Electronic Access at § 495.24(d)(5)(i) for EPs and § 495.24(d)(5)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 6: Coordination of Care Through Patient Engagement

For Stage 3, as previously noted, we proposed to incorporate the Stage 2

objectives related to providing patients with access to health information into a new Stage 3 objective entitled, "Patient Electronic Access" (see section II.B.2.b.v). For this objective 6 entitled "Coordination of Care through Patient Engagement," we proposed to incorporate the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the measure of patient engagement requiring patients (or their authorized representatives) to view, download, and transmit their health information using the functionality of the CEHRT.

Proposed Objective: Use communications functions of CEHRT to engage with patients or their authorized representatives about the patient's care.

The Stage 3 proposed rule focused on encouraging the use of EHR functionality for secure dialogue and efficient communication between providers, care team members, and patients about their care and health status, as well as important health information such as preventative and coordinated care planning. Similar to the Patient Electronic Access Objective, we also proposed to expand the options through which providers may engage with patients under the Medicare and Medicaid EHR Incentive Programs including the use of APIs. An API can enable a patient—through a third-party application—to access and retrieve their health information from a care provider in a way that is most valuable to that patient. We proposed the Coordination of Care through Patient Engagement Objective for Stage 3 to support this provider and patient engagement continuum based on the foundation already created within the EHR Incentive Programs but using new methods and expanded options to advance meaningful patient engagement and patient-centered care. We also proposed that for purposes of this objective, patient engagement may include patient-centered communication between and among providers facilitated by authorized representatives of the patient and of the EP, eligible hospital, or CAH.

We proposed three measures for this objective, which are discussed below. We proposed that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Coordination of Care through Patient Engagement Objective.

Comment: Commenters supported the concept of patient engagement and promoting communication among provider and patients. Also,

commenters supported the changes we proposed to expand the technologies and methods by which providers and patients can leverage technology to support communication and care coordination. Commenters also commended us for the provision allowing providers to attest to all three measures but only meet the threshold for 2 of the 3 in order to pass the measure. Comments stated that this would allow us to collect meaningful data but not penalize providers for variation in their patient populations or other factors that might impact their performance.

Response: We thank the commenters for their support of the objective and our approach to provide flexibility while continuing to encourage a wide range of use cases for patient engagement. We agree that the open communication between provider and patient is a fundamental factor in patient-centered care and effective care coordination. This was a driver behind our proposal for this objective to improve and enhance the channels of communication through supporting health IT solutions.

Comment: Some commenters disagreed with our approach and stated that we should not enforce provider and patient communication through the use of health IT. Commenters claimed that elderly populations, economically disadvantaged populations, patients living in rural areas, and patients with disabilities may not want to use technology to engage with their provider and this makes the requirement unfair to providers serving these patient populations.

Response: First, we disagree that any universal demographic factor would prohibit a patient from using or leveraging technology to communicate with a provider. ONC's research found that there were no significant differences in use of online medical records by age, race/ethnicity, education or setting.¹⁶ We note that assistive technologies, telemedicine technologies, and affordable mobile technologies already exist in the marketplace to serve a wide range of individuals coming from a wide range of backgrounds and we believe that health IT communications technologies will find similar utilization. Second, we recognize that technology supported communication may not be adopted by each patient, which is why we did not propose requiring that a provider ensure all patients actually take action and engage in this manner. However, we note that we do not believe that potential challenges to online or electronic

communications are in any way more significant than the existing challenges to communication posed by the current limited channels available. Nor do we note a causal relationship or correlation between communications challenges and a diminished need or interest in communicating with one's provider. Therefore, we are aiming to support a wide range of communication channels, technologies, and approaches to support many use cases.

Proposed Measure 1: During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, eligible hospital or CAH may meet the measure by either:

(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

(2) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

Proposed Option 1: View, Download, or Transmit to a Third Party

Denominator: Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information.

Threshold: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Proposed Option 2: API

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an ONC-certified API.

¹⁶ ONC Data Brief June 2015 *healthit.gov*.

Threshold: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: Applicable for either option discussed previously, the following providers may exclude from the measure:

- Any EP who has no office visits during the EHR reporting period may exclude from the measure.
- Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC¹⁷ on the first day of the EHR reporting period may exclude from the measure.
- Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

For measure 1, for the API option, we proposed that providers must attest that they have enabled an ONC-certified API and that at least one application, which leverages the API, is available to patients (or the patient-authorized representatives) to retrieve health information from the provider's CEHRT. We also stated that we recognize that there may be inherent challenges in measuring patient access to CEHRT through third-party applications that utilize an ONC-certified API, and we solicited comment on the nature of those challenges and what solutions can be put in place to overcome them. We also solicited comment on suggested alternate proposals for measuring patient access to CEHRT through third-party applications that utilize an API, including the pros and cons of measuring a minimum number of patients (one or more) who must access their health information through the use of an API in order to meet the measure of this objective.

Comment: Similar to the objective in general, a large number of commenters opposed this measure stating providers should not be held accountable for patient action. However, those commenters in support of the measure concept recommended that it be measured as a combination of use cases rather than independently for each function. These commenters approved the inclusion of the API function noting that it offers greater flexibility for patients, but stated that providers

should not be required to meet separate thresholds for patient use of the different functions. They stated that the use of APIs is currently self-selective among patient populations, which skew the provider's ability to push their use universally. Additionally, they noted issues related to independently counting the usage of a function. For example, an API may not be designed to recognize individual instances of use separately over time; it may not independently recognize an action which might also meet the view, download, or transmit actions; or it may prohibit providers who wish to switch to an API assisted VDT system from being able to also meet a separate VDT threshold. However, both commenters in support of the measure and opposed to the measure suggested a lower threshold in order to ensure that providers can meet the requirements by 2018. Some commenters suggested an approach where the threshold increases over time to allow providers to work toward incrementally increased levels. Commenters noted that this would allow providers more time to innovate workflows and methods to overcome barriers to patient engagement.

Response: As noted previously, we disagree that providers have no role in influencing patient engagement. In this new measure for Stage 3, we are seeking to enhance a provider's ability to influence patient engagement by providing a wider range of technologies and methods for a patient's use. We agree with the commenters' recommendation against independent thresholds for the functions within the objective and reiterate our view that there are four actions a patient might take:

1. View their information.
2. Download their information.
3. Transmit their information to a third party.
4. Access their information through an API.

We further agree that these actions may overlap and that a provider should be able to count any and all actions in the single numerator. Therefore, we believe it is a reasonable modification to change the first measure to state that a provider may meet a combined threshold of for VDT and API actions or if their technology functions overlap then any and view, download, transmit, or API actions taken by the patient using CEHRT would count toward the threshold.

We do agree that the threshold should represent a goal, but that we should seek to set a goal that will be attainable for providers who make the effort to achieve this measure. As noted in

section II.B.1.b.(4)(b)(iv) of this final rule with comment period, we adopted a phased approach for the two measures related to patient action for reporting in 2015 through 2017 (Objective 8—Patient Electronic Access measure 2 and the Objective 9—Secure Electronic Messaging.) This phased approach includes a 5 percent threshold in 2017, and we believe it is appropriate to adopt a 5 percent threshold for measures 1 of this objective also (Objective 6—Coordination of Care through Patient Engagement) for an EHR reporting period in 2017. We believe that the primary barrier to performance on the measure is the lag in the adoption of technology by patients as well as the influence of self-selective participation. We further believe that these influences can be mitigated by providing additional time for the technologies to mature as noted in our rationale for adoption of the phased approach. Therefore, it is appropriate for the 5 percent threshold in 2017 to apply for all applicable measures based on the timeline established.

We believe that 10 percent is a reasonable threshold for providers participating in 2018 as compared to the proposed 25 percent threshold, and should be attainable by providers. In addition, we will continue to monitor performance on the measure to determine if any further adjustment is needed prior to 2018 and to potentially set another incremental increase toward the proposed 25 percent threshold in a subsequent year.

Proposed Measure 2: For more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative).

Denominator: Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient, the patient's authorized representatives, or in response to a secure message sent by the patient.

Threshold: The resulting percentage must be more than 35 percent in order for an EP, eligible hospital, or CAH to meet this measure.

¹⁷ www.broadbandmap.gov.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

For measure 2, we proposed that “communicate” means when a provider sends a message to a patient (or the patient’s authorized representatives) or when a patient (or the patient’s authorized representatives) sends a message to the provider. In patient-to-provider communication, the provider must respond to the patient (or the patient’s authorized representatives) for purposes of this measure. We further proposed to include in the measure numerator situations where providers communicate with other care team members using the secure messaging function of CEHRT, and the patient is engaged in the message and has the ability to be an active participant in the conversation between care providers. However, we sought comment on how this action could be counted in the numerator, and the extent to which that interaction could or should be counted for eligible providers engaged in the communication. In addition, we sought comment on what should be considered a contribution to the patient-centered communication; for example, a contribution must be active participation or response, a contribution may be viewing the communication, or a contribution may be simple inclusion in the communication.

We specified that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the provider is the best judge of what health information should be considered relevant in this context. We noted that messages with content exclusively relating to billing questions, appointment scheduling, or other administrative subjects should not be included in the numerator. For care team secure messaging with the patient included in the conversation, we also believe the provider may exercise discretion if further communications

resulting from the initial action should be excluded from patient disclosure to prevent harm. We noted that if such a message is excluded, all subsequent actions related to that message would not count toward the numerator.

Comment: Commenters overwhelmingly supported our approach to the redesigned secure electronic messaging objective for Stage 3. Specifically, commenters noted that this more dynamic, multi-directional objective is a better approach for meeting the underlying goal of effective provider-patient communication than our prior Stage 2 objective.

Specifically, commenters also supported the ability for providers to select to focus on this measure rather than on measure 1 as for some specialists, the ability to quickly and effectively communicate with a patient and other care team members is paramount. These commenters noted that for their patients, the information they provide through VDT is often duplicative of that provided by the patient’s primary care provider. However, they note they often receive request for clarification around specific results or recommendations so the ability to provide that support through secure messaging with the patient and other care team members is a significant benefit.

Some commenters opposed the measure in general, again highlighting that providers should not be held accountable for patient action. Still others disagreed with the requirement that a provider must respond to a patient-initiated communication in order for such an action to count in the numerator.

Again, commenters both opposed to and in support of the measure suggested a lower threshold to ensure the measure is attainable for providers who make the effort to engage in this action. Finally, some commenters requested clarity about what the content of the message needs to be to count toward the numerator.

Response: We appreciate the support and agree with the commenters’ assessment that the Stage 2 objective did not fully meet the intended goal of secure messaging. We agree that this proposed objective supports a wider range of use and a more effective method of communication for providers and patients.

We disagree that this proposed measure holds providers accountable for patient action, as the Stage 3 proposed measure specifically puts the control over communications in the hands of the provider. For this measure, we proposed to include provider-initiated

communications, provider-to-provider communications if the patient is included, and allows the provider to count any patient-initiated communication if the provider responds to the patient (80 FR 16757). We disagree that the provider should not be required to respond to the patient in order to meet the measure, the goal of the measure is to promote provider-patient communication where the action driving the communication rests with provider initiated communication. We note that this does not require the provider to respond to every message received if no response is necessary. In addition, the denominator is not based on the number of messages received from the patient nor are patient-initiated messages required to meet the measure. Therefore we believe that it is reasonable to only allow providers to count messages in the numerator when the provider participates in the communication, in this case by responding to the patient.

Again, we do agree that the threshold should represent a goal, but that we should seek to set a goal that will be attainable for providers who make the effort to achieve this measure. As discussed for Measure 1, we adopted a phased approach for the two measures related to patient action for reporting in 2015 through 2017 (Objective 8—Patient Electronic Access measure 2 and the Objective 9—Secure Electronic Messaging.) This phased approach includes a 5 percent threshold in 2017 and we believe it is appropriate to adopt a 5 percent threshold for measures 2 of this objective (Stage 3 Objective 6—Coordination of Care through Patient Engagement) for an EHR reporting period in 2017. In this case, it is not the barrier of patient action which is a potential risk factor, as the measure itself has been changed, but instead the adoption of new CEHRT and implementing the related workflows which would be required for providers participating in Stage 3 in 2017. We also believe a 25 percent threshold would be an attainable goal for providers in 2018 because the measure focuses on provider-initiated action and offers multiple paths for success; while the reduction from 35 percent reduces the risk of failure for those providers who may require additional time to implement the functions and workflows within their practice. As stated in the Stage 3 proposed rule (80 FR 16757), the types of communications which cannot count toward the measure are communications dealing exclusively with billing, appointment scheduling, or other administrative processes.

Proposed Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Denominator: Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the CEHRT into the patient record.

Threshold: The resulting percentage must be more than 15 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

For measure 3, we noted that the use of the term “clinical” means different things in relation to place of service for billing for Medicare and Medicaid services. However, for purposes of this measure only, we proposed that a non-clinical setting be defined as a setting with any provider who is not an EP, eligible hospital or CAH as defined for the Medicare and Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EP, eligible hospital, or CAH’s CEHRT. This may include, but is not limited to, health and care-related data from care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers, as well as data obtained from patients themselves. We specifically noted this last item and referred to this sub-category as patient-generated health data, which may result from patient self-

monitoring of their health (such as recording vital signs, activity and exercise, medication intake, and nutrition), either on their own, or at the direction of a member of the care team.

We sought comment on how the information for measure 3 could be captured, standardized, and incorporated into an EHR. For the purposes of this measure, the types of data that would satisfy the measure is broad. It may include, but is not limited to, social service data, data generated by a patient or a patient’s authorized representative, advance directives, medical device data, home health monitoring data, and fitness monitor data.

We also sought comment on whether this proposed measure should have a denominator limited to patients with whom the provider has multiple encounters, such as unique patients seen by the provider two or more times during the EHR reporting period. We also sought comment on whether this measure should be divided into two distinct measures—for example, (1) patient-generated health data, or data generated predominantly through patient self-monitoring rather than by a provider; and (2) all other data from a non-clinical setting. This would result in the objective including four measures, with providers having an option of which two measures to focus on for the EHR reporting period.

We also sought comment on whether the third measure should be proposed for eligible hospitals and CAHs, or remain an option only for eligible professionals. For those commenters who believe it should not be applicable for eligible hospitals and CAHs, we sought further comment on whether eligible hospitals and CAHs should then choose one of the remaining two measures or be required to attest to both. We received the following comments and our response follows:

Comment: Commenters were supportive of the concept of the measure with a specific emphasis on the ability to incorporate this type of data into a patient record. Commenters felt this measure specifically supports chronic disease management and care coordination. Commenters recommended that the denominator be limited to two or more visits in a year, which would make the measure more relevant for hospitals and CAHs as well as some types of specialists. Commenters recommended against splitting the measure into two parts and noted that the threshold proposed is too high for a measure that is entirely new.

A number of commenters opposed the measure, expressed concern over the

efficacy of data originating from a source other than a clinician, stated that patient generated data is not relevant to their practice, or stated that all data is patient generated so the measure is useless.

Most commenters requested further information on what types of data would count toward the measure. Some commenters asked if provider questionnaires sent via secure message might count while others asked if patient self-assessment screenings done in the physician’s office may count. Some commenters questioned whether a patient that provided information on family health history may count toward the measure if the information were provided outside an office visit via an electronic means. Finally, commenters requested an episodic designation for the measure to identify when the inclusion of such information must occur and if the inclusion must be repetitive for each EHR reporting period.

Response: We thank the commenters for their input. We agree with the recommendation to maintain a single measure as we believe this best represents the goal of the policy to support the use of CEHRT to incorporate many kinds of data into a comprehensive record for each patient. We are declining the recommended changes to limit the denominator as we believe a wider range is more suitable. However, we agree with the recommendation to reduce the required threshold for this new measure and function to promote adoption with an attainable goal. We are therefore reducing the threshold to 5 percent for the measure. For the purposes of this measure, we note our intent as stated in the Stage 3 proposed rule (80 FR 16757) that the types of data that would satisfy the measure are broad. It may include, but is not limited to, social service data, data generated by a patient or a patient’s authorized representative, advance directives, medical device data, home health monitoring data, and fitness monitor data. In addition, the sources of data vary and may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient-reported outcome data, and other methods of input for patient and non-clinical setting generated health data. We emphasized that these represent several examples of the data types that could be covered under this measure. We note that providers in non-clinical settings may include, but are not limited to, care

providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers. Other key providers in the care team such as behavioral health care providers, may also be included, and we encourage providers to consider ways in which this measure can incorporate this essential information from the broader care team. We also note, as stated in the Stage 3 proposed rule, while the scope of data covered by this proposed measure is broad, it may not include data related to billing, payment, or other insurance information (80 FR 16757).

We also disagree with the suggestion that the data may be information the patient provides to the EP, eligible hospital or CAH on location during the office visit or hospital stay as such data does not meet the intent of the measure to support care coordination and patient engagement in a wide range of settings outside the provider's immediate scope of practice. However, we agree that if a patient separately provides clinical information including family health history and the information noted previously through other means, that such information may count toward the numerator if it is incorporated into the patient record using the adopted specifications for CEHRT for the measure.

With regard to the efficacy of the data, we do not specify the manner in which providers are required to incorporate the data. Providers may work with their EHR developers to establish the methods and processes which work best for their practice and needs. We note that in cases where the data provided can be easily incorporated in a structured format or into an existing field within the EHR (such as a C-CDA or care team member reported vital signs or patient reported family health history and demographic information) the provider may elect to do so. Alternately, a provider may maintain an isolation between the data and the patient record and instead include the data by other means such as attachments, links, and text references again as best meets their needs. We believe there may be a wide range of potential methods by which a provider may ensure the data is relevant for their needs and that provenance and purpose are identified.

Finally, we note that measure 3 includes longitudinal measurement within the EHR reporting period, rather than purely episodic measurement. This means that for more than 5 percent of unique patients during the EHR reporting period, this information must be included. If information is obtained and incorporated for a patient following

their first visit during the EHR reporting period, the provider may count the patient in the numerator even if no further information is provided after a subsequent visit.

After consideration of public comments received, we are finalizing the objective with a modification to remove the reference to communications functions due to the adoption of the use of an API (which is broader than a communication function). We are finalizing the exclusions as proposed and the measures with the modifications for the threshold as previously discussed. We are finalizing that providers must attest to all three measures and must meet the thresholds for at least two measures to meet the objective. We are adopting finalizing the objective and measures as follows:

Objective 6: Coordination of Care Through Patient Engagement

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

Measure 1: During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and either:

- (1) View, download or transmit to a third party their health information; or
- (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or
- (3) a combination of (1) and (2).

- *Denominator:* Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the EHR reporting period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the EHR reporting period.

- *Threshold for 2017:* The resulting percentage must be more than 5 percent.

- *Threshold for 2018 and Subsequent Years:* The resulting percentage must be more than 10 percent.

Measure 2: For more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient or their authorized representative. For an EHR reporting period in 2017, the threshold for this measure is 5 percent rather than 25 percent.

- *Denominator:* Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the EHR reporting period.

- *Threshold in 2017:* The resulting percentage must be more than 5 percent in order for an EP, eligible hospital, or CAH to meet this measure

- *Threshold in 2018 and Subsequent Years:* The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Measure 3: Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Denominator:* Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- *Numerator:* The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the CEHRT into the patient record during the EHR reporting period.

- *Threshold:* The resulting percentage must be more than 5 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: A provider may exclude the measures if one of the following apply:

- An EP may exclude from the measure if they have no office visits during the EHR reporting period.

- Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We are adopting Objective 6: Coordination of Care Through Patient Engagement at § 495.24(d)(6)(i) for EPs and § 495.24(d)(6)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 7: Health Information Exchange

In the Stage 3 proposed rule 80 FR 16758, we stated that improved communication between providers caring for the same patient can help providers make more informed care decisions and coordinate the care they provide. Electronic health records and the electronic exchange of health information, either directly or through health information exchanges, can reduce the burden of such communication. We noted that the purpose of the proposed objective is to ensure a summary of care record is transmitted or captured electronically and incorporated into the EHR for patients seeking care among different providers in the care continuum, and to encourage reconciliation of health information for the patient. We further stated that the proposed objective promotes interoperable systems and supports the use of CEHRT to share information among care teams.

Proposed Objective: The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other

providers into their EHR using the functions of CEHRT.

In the Stage 2 final rule at 77 FR 53983, we described transitions of care as the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. For additional information, see section II.B.1.b.(4).(f) of this final rule with comment period. Referrals are cases where one provider refers a patient to another provider, but the referring provider also continues to provide care to the patient. We also recognized there may be circumstances when a patient refers himself or herself to a setting of care without a provider's prior knowledge or intervention. These referrals may be included as a subset of the existing referral framework and they are an important part of the care coordination loop for which summary of care record exchange is integral. Therefore, a provider should include these instances in their denominator for the measures if the patient subsequently identifies the provider from whom they received care. In addition, the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care.

In the Stage 2 final rule, we indicated that a transition or referral within a single setting of care does not qualify as a transition of care (77 FR 53983). We received public comments and questions requesting clearer characterization of when a setting of care can be considered distinct from another setting of care. For example, questions arose whether EPs who work within the same provider practice are considered the same or two distinct settings of care. Similarly, questions arose whether an EP who practices in an outpatient setting that is affiliated with an inpatient facility is considered a separate entity. Therefore, in the Stage 3 proposed rule at 80 FR 16759 for the purposes of distinguishing settings of care in determining the movement of a patient, we explained that for a transition or referral, it must take place between providers which have, at minimum, different billing identities within the EHR Incentive Programs, such as different National Provider Identifiers (NPI) or hospital CMS Certification Numbers (CCN) to count toward this objective.

Please note that a "referral" as defined here only applies to the EHR Incentive Programs and is not applicable to other federal regulations.

We stated in the Stage 2 final rule at 77 FR 13723 that if the receiving provider has access to the medical record maintained by the provider initiating the transition or referral, then the summary of care record would not need to be provided and that patient may be excluded from the denominators of the measures for the objective. We further noted that this access may vary from read-only access of a specific record, to full access with authoring capabilities, depending on provider agreements and system implementation among practice settings. In many cases, a clinical care summary for transfers within organizations sharing access to an EHR may not be necessary, such as a hospital sharing their CEHRT with affiliated providers in ambulatory settings who have full access to the patient information. However, public comments received and questions submitted by the public on the Stage 2 Summary of Care Objective reveal that there may be benefits to the provision of a summary of care document following a transition or referral of a patient, even when access to medical records is already available. For example, a summary of care document would notify the receiving provider of relevant information about the latest patient encounter as well as highlight the most up-to-date information. In addition, the "push" of a summary of care document may function as an alert to the recipient provider of the transition that a patient has received care elsewhere and would encourage the provider to review a patient's medical record for follow-up care or reconciliation of clinical information.

Therefore, we proposed to revise this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT, as long as the providers have different billing identities within the EHR Incentive Program. We noted that for a transition or referral to be included in the numerator, if the receiving provider already has access to the CEHRT of the initiating provider of the transition or referral, simply accessing the patient's health information does not count toward meeting this objective. However, if the initiating provider also creates and sends a summary of care document, this transition can be included in the denominator and the numerator, as long as this transition is counted consistently across the organization.

Proposed Measures: We proposed that providers must attest to the numerator and denominator for all three measures,

but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Health Information Exchange Objective.

Proposed Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Proposed Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

Proposed Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

- *Medication allergy.* Review of the patient's known medication allergies.

- *Current Problem list.* Review of the patient's current and active diagnoses.

For the first measure, we maintained the requirements established in the Stage 2 final rule to capture structured data within the certified EHR and to generate a summary of care document using CEHRT for purposes of this measure (77 FR 54014). For purposes of this measure, we required that the summary of care document created by CEHRT be sent electronically to the receiving provider.

In the Stage 2 final rule at 77 FR 54016, we specified all summary of care documents must include the following information in order to meet the objective, if the provider knows it:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Encounter diagnosis.
- Immunizations.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI).
- Smoking status.

- Functional status, including activities of daily living, cognitive and disability status.

- Demographic information (preferred language, sex, race, ethnicity, date of birth).

- Care plan field, including goals and instructions.

- Care team including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider.

- Discharge instructions (Eligible hospitals and CAHs Only).

- Reason for referral (EP only).

For the 2015 Edition proposed rule, ONC proposed a set of criteria called the Common Clinical Data Set that include the required elements for the summary of care document, the standards required for structured data capture of each, and further definition of related terminology and use. Therefore, for Stage 3 of meaningful use we proposed that summary of care documents used to meet the Stage 3 Health Information Exchange objective must include the requirements and specifications included in the CCDS specified by ONC for certification to the 2015 Edition proposed rule.

In the Stage 3 proposed rule (80 FR 16760), we stated that the CCDS may include additional fields beyond those initially required for Stage 2 of meaningful use as new standards are developed to accurately capture vital information on patient health. For example, the 2015 Edition proposed rule includes a criterion and standard for capturing the unique device identifier (UDI) for implantable medical devices. As we noted in the Stage 3 proposed rule at 80 FR 16760, we believe the inclusion of the UDI in the CCDS reflects the understanding that UDIs are an important part of patient information that should be exchanged and available to providers who care for patients with implanted medical devices. The documentation of UDIs in a patient medical record and the inclusion of that data field within the CCDS requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety. This example highlights the importance of capturing health data in a structured format using specified, transferable standards. For further information on the CCDS standards, please see ONC's 2015 Edition final rule, published elsewhere in this issue of the **Federal Register**. In circumstances where there is no information available to populate one or more of the fields included in the CCDS, either because the EP, eligible hospital,

or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests) the EP, eligible hospital, or CAH may leave the field blank and still meet the requirements for the measure.

However, all summary of care documents used to meet this objective must be populated with the following information using the CCDS certification standards for those fields:

- Current problem list (Providers may also include historical problems at their discretion).

- Current medication list.

- Current medication allergy list.

We defined allergy in the proposed rule as an exaggerated immune response or reaction to substances that are generally not harmful (80 FR 16760). Information on problems, medications, and medication allergies could be obtained from previous records, transfer of information from other providers (directly or indirectly), diagnoses made by the EP or hospital, new medications ordered by the EP or in the hospital, or through querying the patient.

We proposed to maintain that all summary of care documents contain the most recent and up-to-date information on all elements. In the event that there are no current diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies; the EP, eligible hospital, or CAH must record or document within the required fields that there are no problems, no medications, or no medication allergies recorded for the patient to satisfy the measure of this objective. The EP or hospital must verify that the fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP, eligible hospital, or CAH as of the time of generating the summary of care document.

In the Stage 3 proposed rule 80 FR 16760, we encouraged providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

Similarly, we noted comments from stakeholders and through public forums and correspondence on the potential of allowing only clinically relevant

laboratory test results and clinical notes (rather than all laboratory tests results and clinical notes) in the summary of care document for purposes of meeting the objective. We stated our belief that while there may be a benefit and efficiency to be gained in the potential to limit laboratory test results or clinical notes to those most relevant for a patient's care; a single definition of clinical relevance may not be appropriate for all providers, all settings, or all individual patient diagnosis. Furthermore, we noted that should a reasonable limitation around a concept of "clinical relevance" be added, a provider must still have the CEHRT functionality to include and send all labs or clinical notes. Therefore, we proposed to defer to provider discretion on the circumstances and cases in which a limitation around clinical relevance may be beneficial and note that such a limitation would be incumbent on the provider to define and develop in partnership with their health IT developer as best fits their organizational needs and patient population. In the Stage 3 proposed rule 80 FR 16760 we further specified our proposal that while the provider has the discretion to define the relevant clinical notes or relevant laboratory results to send as part of the summary of care record, to state that providers must be able to provide all clinical notes or laboratory results through an electronic transmission of a summary of care document if that level of detail is subsequently requested by a provider receiving a transition of care or referral or the patient is transitioning to another setting of care. We noted that this proposal would apply for lab results, clinical notes, problem lists, and the care plan within the summary of care document.

For the second measure, we proposed to address the other end of the transition of care continuum. In the Stage 2 final rule, we limited the action required by providers to sending an electronic transmission of a summary of care document (77 FR 54017 through 54018). We did not have a related requirement for the recipient of that transmission. We did not adopt a certification requirement for the receiving end of a transition or referral or for the measure related to sending the summary, as that is a factor outside the sending provider's immediate control. However, in Stage 3 of meaningful use, we proposed a measure for the provider as the recipient of a transition or referral requiring him or her to actively seek to incorporate an electronic summary of care document into the patient record when a patient

is referred to them or otherwise transferred into their care. This proposal was designed to complete the electronic transmission loop and support providers in using CEHRT to support the multiple roles a provider plays in meaningful health information exchange.

For the purposes of defining the cases in the denominator, we proposed that what constitutes "unavailable" and, therefore, may be excluded from the denominator, will be that a provider—

- Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.

We sought comment on whether electronic alerts received by EPs from hospitals when a patient is admitted, seen in the emergency room or discharged from the hospital—so called "utilization alerts"—should be included in measure 2two, or as a separate measure. Use of this form of health information exchange is increasingly rapidly, driven by hospital and EP efforts to improve care transitions and reduce readmissions. We also sought comment on which information from a utilization alert would typically be incorporated into a patient's record and how this is done today.

For both the first and second measures, we proposed that a provider may use a wide range of health IT systems for health information exchange to receive or send an electronic summary of care document, but must use their certified EHR technology to create the summary of care document sent or to incorporate the summary of care document received into the patient record. We also proposed that the receipt of the summary of care document may be passive (provider is sent the C-CDA and incorporates it) or active (provider requests a direct transfer of the C-CDA or provider queries an HIE for the C-CDA). In the Stage 2 proposed rule, we noted the benefits of requiring standards for the transport mechanism for health information exchange consistently nationwide (77 FR 13723). In the Stage 2 final rule, a governance mechanism option was included in the second measure for the summary of care objective at 77 FR 54020. In the Stage 3 proposed rule 80 FR 16762, we again sought comment on a health information exchange governance mechanism. Specifically we sought comment on whether providers who

create a summary of care record using CEHRT for purposes of Measure 1 should be permitted to send the created summary of care record either—(1) Through any electronic means; or (2) in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We additionally sought comment on whether providers who are receiving a summary of care record using CEHRT for the purposes of Measure 2 should have a similar requirement for the transport of summary of care documents requested from a transitioning provider. Finally, we sought comment on how a governance mechanism established by ONC at a later date could be incorporated into the EHR Incentive Programs for purposes of encouraging interoperable exchange that benefits patients and providers, including how the governance mechanism should be captured in the numerator, denominator, and thresholds for both the first (send) and second (receive) measures of this HIE objective.

For the third measure, we proposed a measure of clinical information reconciliation, which incorporates the Stage 2 objective for medication reconciliation and expands the options to allow for the reconciliation of other clinical information. Clinical information such as medication allergies and problems will allow providers additional flexibility in meeting the measure in a way that is relevant to their scope of practice. In the Stage 2 final rule, we outlined the benefits of medication reconciliation, which enables providers to validate that the patient's list of active medications is accurate (77 FR 54011 through 54012). This activity improves patient safety, improves care quality, and improves the validity of information that the provider shares with others through health information exchange. We believe that reconciliation of medication allergies and problems affords similar benefits.

For this proposed measure, we specified that the EP, eligible hospital, or CAH that receives the patient into their care should conduct the clinical information reconciliation. It is for the receiving provider that up-to-date information will be most crucial to make informed clinical judgments for patient care. We reiterated that this measure does not dictate what subset of information must be included in reconciliation. Information included in the process is determined by the provider's clinical judgment of what is most relevant to patient care.

For this measure, we proposed to define clinical information

reconciliation as the process of creating the most accurate patient-specific information in one or more of the specified categories using the clinical information reconciliation capability of certified EHR technology, which will compare the “local” information to external/incoming information that is being incorporated into the certified EHR technology from any external source. We referred providers to the standards and certification criteria for clinical information reconciliation proposed in ONC’s 2015 Edition proposed rule at 80 FR 16831 through 16833.

As with medication reconciliation, we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing clinical information reconciliation.

We recognized that workflows to reconcile clinical information vary widely across providers and settings of care, and we requested comment on the challenges that this objective might present for providers, and how such challenges might be mitigated, while preserving the policy intent of the measure. In particular, we solicited comment on the following:

- Automation and Manual Reconciliation. The Stage 2 measure does not specify whether reconciliation must be automated or manual. Some providers have expressed concern over the automatic inclusion of data in the patient record from referring providers, while others have indicated that requiring manual reconciliation imposes significant workflow burden. We also sought comment on whether the use and display of meta-tagged data could address concerns related to the origin of data and thereby permit more automated reconciliation of these data elements.

- Review of Reconciled Information. Depending on clinical setting, this measure could be accomplished through manual reconciliation or through automated functionality. In either scenario, should the reconciliation or review of automated functionality be performed only by the same staff allowed under the Stage 3 requirements for the CPOE objective?

- What impact would the requirement of clinical information reconciliation have on workflow for specialists? Are there particular specialties where this measure would be difficult to meet?

- What additional exclusions, if any, should be considered for this measure?

We also encouraged comment on the proposal to require reconciliation of all three clinical information reconciliation

data sets, or if we should potentially require providers to choose 2 of 3 information reconciliation data sets relevant to their specialty or patient population. We explained that we expect that most providers would find that conducting clinical information reconciliation for medications, medication allergies, and problem lists is relevant for every patient encountered. We solicited examples describing challenges and burdens that providers who deliver specialist care or employ unique clinical workflow practices may experience in completing clinical information reconciliation for all three data sets and whether an exclusion should be considered for providers for whom such reconciliation may not be relevant to their scope of practice or patient population. Additionally, we solicited comments around the necessity to conduct different types of clinical information reconciliation of data for each individual patient. For example, it is possible that the data for certain patients should always be reviewed for medication allergy reconciliation, when it may not be as relevant to other patient populations.

We proposed that to meet this objective, a provider must attest to the numerator and denominator for all three measures but would only be required to successfully meet the threshold for two of the three proposed measures.

Measure 1: To calculate the percentage of the first measure, CMS and ONC worked together to define the following for this measure:

Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

Threshold: The percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR

reporting period may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 2: To calculate the percentage of the second measure, CMS and ONC worked together to define the following for this measure:

Denominator: Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

Threshold: The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 3: To calculate the percentage, CMS and ONC worked together to define the following for this measure:

Denominator: Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list, medication allergy list, and current problem list.

Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We received the following comments and our response follows:

Comment: Many commenters supported our proposal for the HIE Objective applauding the focus on interoperability stating the move toward a true ability to share all patient health records in real time, regardless of EHR system in use, is much needed and very valuable to both providers and patients. This would almost certainly allow better management of care, less duplication of tests and reduction of other waste elements in the system, thus reducing costs. Other commenters noted support of the use of CEHRT to transmit a summary of care record during transitions of care and acknowledges the value of incorporating a patient's summary of care record received from another provider to facilitate clinical information reconciliation and care delivery.

Some commenters specifically mentioned that people with cancer often receive fragmented and uncoordinated care because their treatments frequently require multiple clinicians including surgeons, oncologists, primary care physicians, and other specialists. These commenters noted that providing coordinated care requires access to all of a patient's data by all of his or her

providers, an essential function that EHRs can provide.

Still others expressed conceptual support for the proposed objective as the measures rationally seeks to organize the care of the patient on the care continuum and takes the next step in closing the transitions of care loop by incorporating outside medical information and promoting the reconciliation of medical data from transitioning patients. These commenters expressed a belief that the efforts to improve communication between providers for the same patient promotes better care decisions and care coordination. The ability to communicate information electronically decreases the chance of errors, missing information, or misunderstandings due to lack of standardization. Finally many commenters noted that the ability to send and receive data from other providers throughout the care continuum is imperative to transforming healthcare and improving patient care.

Response: We thank the commenters for their support and agree that this objective should be a top priority for delivery system reform to promote the real-time interoperable exchange of health information and facilitate care coordination. We also appreciate the insight on how electronic exchange can support care management through reducing errors and duplicate testing. We believe the benefits of effective health information exchange are extensive for both providers and patients and for this reason we have maintained health information exchange as a key goal of the EHR Incentive Programs.

Comment: The majority of commenters believe the thresholds for health information exchange (HIE) are too high for EPs. They pointed to various interoperability challenges, which make it difficult to meet the requirements and generally state that we are holding providers accountable for industry or national issues surrounding interoperability that are beyond their control.

Many commenters stated that there are not enough providers and practices that can electronically receive transition of care documents because many (especially those in rural areas) do not have the capabilities needed to meet the HIE requirements (for example, Direct technologies, HIE access). Other commenters stated a lack of trading partners, including health care providers who are not subject to these regulations) as one of the main obstacles to meeting the Stage 3 HIE requirements. Several commenters requested that providers only be

required to engage eligible professionals and eligible hospitals who are also working toward meeting the requirements of the EHR Incentive Programs, and that there should be exclusions based on the capabilities of surrounding practices or a lack of trading partners. Other commenters indicated statewide and regional health information exchanges are at varying levels of development and vary widely in their capabilities and sophistication. Other commenters stated the HIE technology and interoperability capabilities are not mature enough to meet these HIE requirements and will lead to provider failure or providers being held responsible for criteria they cannot control and standards they cannot meet.

Another commenter stated there are no national or regional data repositories in place for direct email addresses to be shared which has made it extremely challenging for providers to comply with this objective and measure, even if the provider has the capability to generate and transmit a C-CDA.

Response: We disagree and believe that this threshold is a reasonable and achievable goal for providers for an EHR reporting period in 2018. We understand the challenges providers and other stakeholders describe and recognize that the transition to interoperable health information exchange requires a paradigm shift across the health care industry. We believe the work providers are already engaged in and the HIE objectives and measures from Stage 2 are helping to actualize this change. As described in the Stage 3 proposed rule (80 FR 16739), we believe that electronic exchange is more likely to succeed as a higher volume of providers are actively engaged in the sending and receiving of electronic health information. Further, we note that we have proposed more flexibility in the transport mechanism in order to support the exchange of a standardized file in a wide range of transactions. Therefore, we believe that the requirement of this objective is a challenging goal, but a challenge that can and should be achieved.

We disagree that there should be additional exclusions for this objective. As stated previously, we believe that the increased participation in the EHR Incentive Programs will help to support the overall ability for providers to electronically exchange health information. Further, we note that performance for providers in rural areas on the Stage 2 objective does not differ from the overall performance on the

measure.¹⁸ We also note that, as stated in the proposed rule, we define a transition of care or referral as a transition or referral to another provider of care that is recognized as a different billing entity for the EHR Incentive Programs (NPI, CCN). The inclusion or exclusion of additional provider types and transitions or referrals is at the discretion of the provider as best meets their practice needs as long as the inclusion or exclusion policy is applied universally for the duration of the EHR reporting period.

We intend to support policies that mitigate the impact that a lack of trading partners or a lack of transport mechanisms have on providers. As we note throughout this final rule with comment period, we are seeking to increase participation among EHR Incentive Program participants and expand the methods by which providers may exchange information. These policies are aimed at ensuring that a lack of trading partners will not continue to be a significant hurdle for providers as the widespread adoption of certified EHRs continues and new flexible innovations for transport are supported.

In addition, CMS and ONC share a mutual understanding of the issue relating to importance of provider access to health information exchange contact information and agree that a method to facilitate this access would support interoperable health information exchange. We are committed to exploring potential models and opportunities to enable providers to more readily share their own electronic exchange contact information and access the contact information of potential trading partners. It is our intent to populate the National Plan and Provider Enumeration System (NPPES) with direct addresses and/or electronic service endpoints of EHR Incentive Program participants as a means of creating a health care provider directory resource. For more information, we direct readers to section II.D.3 of this final rule with comment period.

Comment: Many commenters requested a clearer definitions for the denominators relating to the measures including:

- Transitions of care for providers with a shared EHR
- Patient-reported referrals and patient self-referrals
- New patients and patient encounters in which the provider has never before encountered the patient

Commenters further went on to express support for the option to include providers with a shared EHR and support for the ability to include patient-self referrals as an option, and asked specific questions relating to how these items impact any variation in the denominators between the measures.

Response: We refer commenters to the Stage 2 final rule at 77 FR 53982 through 53983 as well as section II.B.1.b.(4).(f) of this final rule with comment period for further explanation of the definition of transitions of care and the definition of transition or referral, which has not been modified from Stage 2.

For our policy regarding transitions or referrals among providers with a shared EHR, in the Stage 3 proposed rule, we proposed that providers may count a transition of care or referral as long as the receiving provider would at least be considered a different provider if attesting for the EHR Incentive Programs (individual NPI or CCN level) in the denominator if they do so universally across all settings. They may also count these transitions with providers who share a certified EHR if they do so universally across all settings and for all such transitions. However, for any action to count in the numerator of a measure within this objective, the provider may not simply deem the shared access to the record sufficient, they would instead need to complete the required action associated with each measure. We maintain that this option to include or not include such transitions is entirely at the provider's discretion, but the policy must be applied universally for all transitions or referrals related to the denominator for Measure 1 and Measure 2. We believe that these transitions and referrals should not be excluded from Measure 3, as clinical information reconciliation may include actions beyond the electronic exchange of a patient record. We further clarify that the use of the reference to a billing identity within the program is intended to establish the baseline that if a provider chooses to include exchanges with providers with a shared EHR they may do so as long as the recipient would be considered a different provider in the EHR Incentive Programs (e.g., by the EPs NPI or the eligible hospital or CAH CCN). Some examples which would be included under this policy would be one EP sending to another EP in the same group practice, an eligible hospital sending to an EP in an ambulatory setting which shares the hospital EHR, or a provider sending to a non-EP practitioner who may have shared access to the EHR but whose patient encounters are not

included under the referring EPs supervision. Some examples which would be excluded under the policy are an EP in one setting referring a patient to another setting for a different service but where the same EP is the provider, an eligible hospital referring a patient from one clinical setting within the hospital to another (where they attest with the same CCN), and an EP sending to a non-EP practitioner who is under direct supervision and whose patient encounters may be included in the EPs attestation.

We note that in the Stage 3 proposed rule (80 FR 16759) we stated that we believe a provider should count a referral in the denominator in the case of patient-self referrals if the patient subsequently identifies the provider from whom they received care. We further stated that the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care. However, we have reconsidered this requirement based on feedback from commenters who note that variations in timing and provider specialty might impact the feasibility and value proposition for a provider to count patient self-referrals in this manner. For example, if a primary care provider is notified of a self-referral to a specialist months after the resulting visit with the specialist has occurred, the receipt and incorporation (Measure 2) and reconciliation (Measure 3) of the summary of care record by the primary care provider from the specialist is important for the patient's continued care by the primary care provider. In this scenario, it may not make sense for Measure 1 to be required. Under measure 1 as proposed, the primary care provider would be required to send a summary of care record to the specialist. If the specialist has already seen the patient and no follow-up or continued treatment is needed, we believe the referring provider is best suited to determine whether the summary of care record should still be sent. We note that there are further examples of such instances which provide further complications for feasibility of this requirement as proposed. We are, therefore, modifying our initial proposal so that patient self-referrals may be included, but are not required, for measure 1. The provider should determine in what cases they would include or not include patient-self referrals and apply that policy across all such referrals for the duration of the reporting period. We note that providers

¹⁸ ONC Data Brief June 2015 healthit.gov.

should seek to receive or retrieve a summary of care document from the other provider of care and should seek to reconcile clinical information once the provider is identified in the same manner they would for any other transition or referral for measures 2 and 3.

For the definition of new patient and never before seen by the provider, we stated that we use the same definition of “new patient” as described in Objective 7 Medication Reconciliation for the EHR Incentive Programs in 2015 through 2017 in section II.B.2.a.v of this final rule with comment period.

Comment: Some commenters opposed the option to allow providers to only meet the threshold for 2 of 3 objectives, suggesting this would result in slower adoption of true interoperability between providers as they pursue different goals of the EHR Incentive Programs. These commenters stated that providers need to align on common goals to successfully reach interoperability. Other commenters praised this flexibility stating that it would allow them to set internal goals and a continuous improvement process and still be able to meet program requirements if they sought to make adjustments to workflows.

Response: We appreciate the insights from the commenters and agree that the allowance to meet two of three thresholds represents a more flexible option for providers. We believe that rather than hinder participation, this flexibility will allow providers to innovate and expand their uses of HIE as best meets their organizational needs.

Comment: Many commenters supported our proposal allowing providers to limit the transmission of certain data elements based on clinical relevance. Others commended the approach of requiring the ability to send all data elements while allowing flexibility for providers to make the determination of relevance as best fits their practice and patient population.

Some commenters further suggested that providers be able to limit the C-CDA itself or not be required to send the full C-CDS on all transitions of care. Many commenters addressed the C-CDS itself stating that they support renaming the clinical data sets from “Common MU Data Set” to a new term, as the data sets are relevant beyond the EHR Incentive Programs. Some noted that CCDS is close to C-CDA however commenters were split on if that was a problem or a benefit.

Some commenters opposed the changes to the required data set in the CCDS stating that the additional data fields that are incorporated into the

proposed Stage 3 CCDS would involve significant effort to implement and transition the data elements necessary to support the standard summary of care record.

Other commenters noted agreement with the expansion of captured data elements and recommended we maintain capture of this information in a format supported by the C-CDA data structure, but that they should not be mandatory to be populated on the C-CDA in order to meet the numerator of sending an electronic summary of care. These commenters supported continuing to require that the current problem list, medication list, and medication allergy must be populated within the C-CDA.

Response: We thank the commenters and note that our proposal to allow for provider discretion over clinical relevance stemmed largely from the input from providers on how best to address issues with this measure. We also agree that it is essential to maintain the ability to send a full set of all available lab results and clinical notes. We reiterate that while the provider generally has the discretion to define the relevant clinical notes or relevant laboratory results, providers must be able to provide all clinical notes and/or laboratory results through an electronic transmission of a summary of care document. Furthermore, providers must send all clinical notes and/or all laboratory results if that level of detail is subsequently requested by a provider receiving a transition of care or referral, or if that level of detail is requested by the patient who is transitioning to another setting of care.

We disagree with the suggestion that the C-CDA not be required and that any electronic transmission of patient health information may be accepted for attestation. Furthermore, we disagree with suggestions that the C-CDA should not include all required elements of the ONC defined CCDS for purposes of CEHRT. We note that both the CCDS and C-CDA support the interoperable exchange of data elements for provider use. Without standards, the data from one system cannot readily be translated into usable data in another system.

However, we clarify that not all elements of the CCDS are required to include data if no such data is available or known to the provider. The only three fields which must include data are the current problem list, medication list, and medication allergy list, which must at least include a reference that no such data is known or available. This is an important patient safety element finalized in the Stage 2 final rule which we maintain for Stage 3.

Comment: Some commenters noted the importance of the availability of certain information in care delivery, including sexual orientation & gender identity, disparities, behavior health, and UDI data. Some commenters specifically highlighted the importance of capturing UDI data for improved care and better reporting of adverse events as well as allowing for the ability to provide more effective corrective and preventative action in response to device recalls and alerts.

Response: We thank commenters for their comments and for their support of UDI within the program. We note that ONC’s 2015 Edition final rule, published elsewhere in this issue of the **Federal Register**, includes UDIs for a patient’s implantable devices in the CCDS and the corresponding implantable device list certification criterion in the Base EHR definition. We believe that incorporating UDIs, beginning with UDIs for implantable devices, in certified EHR technology will be integral to patient care, as this information can help those within a patient’s care team to accurately identify the patient’s devices (and associated clinically relevant information, such as a device’s latex content or MRI safety) and thus be better informed and better able to care for the needs of the patient. We refer readers to the 2015 Edition final rule for further discussion of this criteria.

Certain other types of information, while not required within the CCDS, have associated standards and capabilities for data capture that are included in certification criteria that compose the Base EHR definition. As such, while these types of information are not required within the CCDS, the ability to capture this information is required under the definition of CEHRT. This distinction means the provider would have the data element available for use within their certified EHR and would have the ability to capture the data in a structured format as appropriate for their individual practice and patient population. For example, the Base EHR definition included in the 2015 Edition final rule provides for the capture of demographic data within certified EHR technology, including the capture of more granular data on race and ethnicity and of data that extends beyond a more limited understanding of clinical care data—such as the collection of social, psychological, and behavioral health information. The ability to capture this information in CEHRT supports provider efforts to provide improved, patient-centered care and reduce health disparities.

The 2015 Edition proposed rule also included a criterion to record a patient's sexual orientation and gender identity (SO/GI) in a structured way with standardized data. Where the patient chooses to disclose this information, the inclusion of this information can help those within the patient's care team to have more information on the patient that can aid in identifying interventions and treatments most helpful to the particular patient. Additionally, sexual orientation and gender identity can be relevant to individual treatment decisions; for example, transgender men who were assigned female at birth should be offered a cervical exam, as appropriate. In the final rule, ONC is requiring that Health IT modules enable a user to record, change, and access SO/GI to be certified to the 2015 Edition "demographics" certification criterion. By doing so, SO/GI is now included in the 2015 Edition Base EHR definition, which is a part of the definition of CEHRT (see section II.B.3). We note that certification does not require that a provider collect this information; it requires only that their CEHRT enable the provider to do so. CMS and ONC believe including SO/GI in the "demographics" criterion represents a crucial step forward to improving care for LGBT communities.

We also note that we received comments specific to the composition of the CCDS and addressing the C-CDA, which are out of scope for this rule. We refer readers to the 2015 Edition final rule included elsewhere in this **Federal Register** for further information on the CCDS and the C-CDA, as well as for further information on provisions related to data collection, including the collection of sexual orientation and gender identity data and behavioral, social, and psychological data.

Comment: For Measure 1, many commenters expressed similar concerns with the first measure as with HIE as a whole citing interoperability barriers and the lack of providers and other trading partners available to electronically exchange data. Commenters also considered the threshold of 50% to be too high and too far a leap from the 10% requirement in Stage 2. Additionally, commenters opposed removing the exclusion qualifier which allowed providers to exclude the measure if they conduct fewer than 100 referrals or transitions of care during the EHR reporting period. A few commenters believe measure 1 is a valuable driver of interoperability within health care, but acknowledged that refinements/adjustments need to be made.

Response: We reiterate that CMS and ONC are committed to working with the industry to support and promote an expanded HIE infrastructure to facilitate health IT facilitated care coordination. We believe expanding the flexibility for the use of a wide variety of transport mechanisms, encouraging wider provider participation and continuing to support the use of standards for structured data in certified EHR technology will help to mitigate these concerns. We do not believe the threshold is too high given the past performance, the expansion of options, and the expressed need for higher overall participation. We do however note that the change to the exclusion may be problematic for providers with very few transitions in an EHR reporting period and are therefore maintaining the exclusion at 100 transitions and referrals as finalized in the Stage 2 final rule for an electronic summary of care and consistent with measures 2 and 3.

Comment: Some commenters requested clarification if any electronic means could include transmission via pdf or electronic fax, or the conversion of a C-CDA document into one of these formats. Commenters also suggested that any electronic means is not a rigorous enough definition to ensure the security of patient information in transmission.

Many commenters strongly supported the expansion of the available methods by which secure electronic exchange could occur. Some strongly encouraged us to continue to require summary of care record exchange in a manner that is consistent with a governance mechanism ONC establishes for the nationwide health information network. These commenters noted that transmission of a summary of care record could be accomplished in various ways and requested that CMS and ONC should provide resources outside the regulations to support and clarify these requirements for developers and providers.

Other commenters specifically supported the requirement for the transmission of electronic summary of care document in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network and believe that allowing any other transmission method will increase the cost and complexity of receiving and incorporating data into the EHR.

Response: We note that the intent for flexibility around sending via any electronic means (so long as the provider is using the standards established for certified health IT under the ONC certification program for the creation of the electronic summary of

care document) is to promote and facilitate a wide range of options and also to specifically facilitate the receipt of a summary of care document electronically. In the past, in response to inquiries by providers we developed an FAQ which stated that an electronic summary of care document may be converted from a C-CDA to another format (e.g. SOAP, secure email, electronic fax, and etc.) by a third party intermediary, and that such a transition may still be counted in the numerator if the third party can confirm for the sending provider that the summary of care was ultimately received by the next provider of care.¹⁹ However, for Stage 3 we do not intend to continue to allow this policy, as it does not drive toward the overall goal of the HIE Objective that providers send, receive or retrieve, and incorporate an electronic summary of care document for each transition or referral. This means the initiating provider must send a C-CDA document that the receiving provider would be capable of electronically incorporating as a C-CDA on the receiving end. In other words, if a provider sends a C-CDA and the receiving provider converts the C-CDA into a pdf or a fax or some other format, the sending provider may still count the transition or referral in the numerator. If the sending provider converts the file to a format the receiving provider could not electronically receive and incorporate as a C-CDA, the initiating provider may not count the transition in their numerator. We further note that for measure 1, a provider must have confirmation of receipt or that a query of the summary of care record has occurred in order to count the action in the numerator.

We further note that the security of the transmission is of paramount importance to CMS. We, therefore, remind providers and emphasize that any transmission method chosen by a provider must comply with the privacy and security protocols for ePHI outlined in HIPAA.

We requested comment from providers on how the governance mechanism could be considered for purposes of the objectives and measures in Stage 3 and we thank commenters for their comments. We will continue to consider these comments as we work with ONC to address governance as it relates to health information exchange, and look forward to continuing to work with stakeholders in this area.

¹⁹FAQ #10660 <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html> Frequently Asked Questions: EHR Incentive Programs.

Comment: For Measure 2, some commenters acknowledged the potential benefit of this measure with the understanding that various challenges would need to be overcome first. Commenters felt the 40 percent threshold was too high, particularly for a new measure. They also expressed concerns with the administrative burden, workflow and time management challenges, and technological barriers involved in reviewing and incorporating data from other providers.

Response: We respectfully disagree that the threshold for the measure is too high, as the ability to retrieve, receive and incorporate an electronic summary of care document for transitions or referrals as defined by the measure is entirely within the provider's control. For example, in our proposal we allow providers to exclude a patient from the denominator where a reasonable due diligence reveals that no electronic record is available for the patient. This reduces the burden on providers to incorporate the record for only those patients for whom an electronic record is available after their effort to receive, request, or query for an electronic summary of care is successful. We believe there may be many variations in how providers accomplish this measure and believe those workflows and processes are best left to provider discretion.

Comment: Some commenters expressed that it would be unreasonable to include patients never before seen by the provider. These commenters noted that, for example, emergency department workflows are simply incompatible with requirements to try to identify outside sources of summary of care records for walk-in patients. They further noted that the infrastructure for doing this does not exist in most areas and is not likely to exist for several years to come.

Other commenters requested we add the word "electronically" to the measure language so that the measure reads "For 40 percent of transitions or referrals received electronically". Other commenters noted that a provider may have the capacity to query an HIE in their CEHRT, but is unable to do so because there is no HIE in their area or their organization is still in the process of on-boarding with a potential HIE network. These commenters expressed concern that the denominator calculation would not allow them to exclude patients for whom they were unable to query in this instance. Others expressed a similar concern over the understanding of an HIE noting that many do not require the provider to possess additional functionality, but

instead allow a provider to query for a document and receive that document via direct transport from the HIE.

Response: We disagree with the commenters that it is unreasonable to include new patients and note that the example provided about the ability of a hospital to find information on a patient presenting at the emergency department is exactly the type of process that is supported by health IT rather than hindered by it.

We also decline to add the qualifier to the measure to specify only counting existing electronic transitions or referrals in the requirement to receive, request or query for an electronic summary of care record. If we were to change the measure to read "received electronically" it eliminates any further follow up to request or query for an electronic record when an electronic record was not already received with the transition or referral. This change would fundamentally alter the measure and render it meaningless.

The proposed measure denominator already allows providers to exclude patients for whom no electronic document is available after a reasonable effort is made, such as a request to the referring provider and a query of any HIE or service. As stated in the proposed rule, for the purposes of defining the cases in the denominator, we proposed that what constitutes "unavailable" and, therefore, may be excluded from the denominator, will be that a provider—

- Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.

However, we do agree with commenters and are adopting a change to state that the reference to HIE functionality within the denominator calculation should be revised to reflect whether or not there is an HIE from which the provider is able to query and receive a C-CDA using their CEHRT. We are therefore adding an additional qualifier to the statement to include that the HIE functionality supporting a query for a summary of care document is not currently operational in the provider's geographic region or EHR network. Therefore, for the purposes of defining the cases in the denominator, we are modifying our proposal to state that what constitutes, "unavailable" and therefore may be excluded from the denominator,—is as follows:

- The provider requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- The provider either:

1. Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or
2. Confirmed that HIE functionality supporting query for summary of care documents was not operational in the provider's geographic region and not available within the provider's EHR network as of the start of the EHR reporting period.

Comment: Finally, commenters requested information on what the term "incorporated" means in the numerator. Some expressed concerns over the integrity of the information if they are forced to incorporate it into their EHR.

Response: We do not define incorporate, as it may vary among recipient providers based on the providers HIE workflows, their patient population, and based on the referring provider. The record may be included as an attachment, as a link within the EHR, as imported structured data, or the provider may conduct a reconciliation of the clinical information within the record to incorporate this information into the patient record within their EHR. We note that a record cannot be considered to be incorporated if it is discarded without the reconciliation of clinical information or if it is stored in a manner that is not accessible for provider use within the EHR.

Comment: Many commenters supported Measure 3 and clinical information reconciliation with some stating that the measure should be required rather than an option within the objective. Others stated that all three types of information should be required for all care transitions because reconciliation of medications, medication allergies, and current problems is consistent with the requirement to provide the safest care. Many commenters also agreed with the threshold for the measure of more than 80 percent, with some stating that we should simply require all patients for this measure instead.

Some commenters discussed the administrative burden, various workflow challenges involved in reviewing, and incorporating data from other providers including the amount of time required to review inbound summary of care reports. Other commenters discussed how the CCDS are not helpful because they contain too much unnecessary and redundant information as well as the risk associated with receiving summary of care information that has not been

reviewed by a provider in a timely manner.

Other commenters stated that not all new patient referrals require comprehensive data reconciliation. For example a dermatologist evaluating a simple skin lesion or an orthopedist evaluating a painful joint may not need to perform in depth reconciliation to provide quality care.

In addition, many commenters discussed the means of measurement for medications, problems, and allergies such as if duplicate records needed to be reconciled or if data that is verified as requiring no further update would also count toward the measure. Several commenters requested clarification on whether the reconciliation should be automated or manual. Some requested we offer both options to allow providers to choose the means that best fits their practice, and many commenters had concerns about the liability associated with automated reconciliation.

Response: We appreciate the support for the measure; however, we did not propose that this measure should be required for the objective but rather that providers must meet the threshold for two of three measures based on the needs of their practice. We believe that many providers may conduct some form of reconciliation in conjunction with measure 2, or that providers in certain specialties may elect to conduct reconciliation of clinical information even beyond our requirement at all patient encounters. We understand from previous listening sessions and feedback from stakeholders that the summary of care documents sometimes contain an overwhelming amount of information. For this reason, we allow provider discretion to define the relevant clinical notes and/or laboratory results to send in the summary of care document, although we maintain that providers must still have the CEHRT functionality to include and send all labs or clinical notes. We believe this will provide the efficiency sought by stakeholders in their feedback.

We note that this measure builds on the existing Medication Reconciliation Objective for the EHR Incentive Programs in 2015 through 2017 (see section II.B.2.a.v). We agree that this process may include both automated and manual reconciliation to allow the receiving provider to work with both the electronic data provided with any necessary review, and to work directly with the patient to reconcile their health information. We further note that the point of reconciliation is to assist in maintaining the most relevant, complete, and up to date information for a given patient. If no update is

necessary, the process of reconciliation may consist of simply verifying that fact or reviewing a record received on referral and determining that such information is merely duplicative of existing information in the patient record. Both such examples would count toward the measure if the provider established their reconciliation process to include such verification.

Comment: Commenters requested clarification on whether data can be reconciled by non-credentialed staff or by credentialed staff only. Commenters were split on their opinions of whether reconciliation should be conducted by only credentialed medical staff like CPOE or by any staff trained to work with the EHR and enter patient information. Some recommended allowing auto reconciliation of data as long as it is reviewed by credentialed staff or provider. Other commenters stated that non-credentialed staff should be able to reconcile the data, then have it reviewed by credentialed staff.

Response: We require the person entering the order in CPOE to be credentialed medical staff because of the need to review, assess, and potentially act on a CDS based on the order entered. For further discussion, we direct readers to the CPOE objective in section II.B.2.a. of this final rule with comment period. In most cases, clinical information reconciliation may not require the same level of medical training and knowledge and a non-clinical staff person trained to accurately and completely enter patient information may be fully qualified to conduct this task. However, in some instances, further medical knowledge and training may be required, such as if a medication reconciliation triggers a CDS drug-drug intervention. We therefore agree with commenters that non-medical staff may conduct reconciliation under the direction of the provider so long as the provider or other credentialed medical staff is responsible and accountable for review of the information and for the assessment of and action on any relevant CDS.

Comment: A few commenters supported the inclusion of electronic alerts to the EP, when their patient is seen in the emergency department or admitted and/or discharged from the hospital. Other commenters stated that the standard is too vague and the technology too immature for required use at this time and that CMS should allow providers to choose if they wish to participate in this action for the near future.

Response: We decline to finalize an inclusion of electronic alerts at this time. We will continue to review the development of the technology and

standard for potential inclusion in the future.

After consideration of public comments received, we are finalizing the objective with a minor modification to the language to clarify receiving or retrieving a summary of care through query as discussed for measure 2. We are finalizing the measures and exclusions as proposed for EPs, eligible hospitals and CAHs. We are finalizing that providers must attest to all three measures and must meet the thresholds for at least two measures to meet the objective. The final objective and measures are as follows:

Objective 7: Health Information Exchange

Objective: The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- *Denominator:* Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

- *Numerator:* The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

- *Threshold:* The percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- *Exclusion:* A provider may exclude from the measure if any of the following apply:

- Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period.
- Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the

latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

- *Denominator:* Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

- *Numerator:* Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

- *Threshold:* The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- *Exclusion:* A provider may exclude from the measure if any of the following apply:

- Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

- Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered

the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- (1) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

- (2) *Medication allergy.* Review of the patient's known medication allergies.

- (3) *Current Problem list.* Review of the patient's current and active diagnoses.

- *Denominator:* Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

- *Numerator:* The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: Medication list, medication allergy list, and current problem list.

- *Threshold:* The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- *Exclusion:* Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

We are adopting Objective 7: Health Information Exchange at § 495.24(d)(7)(i) for EPs and § 495.24(d)(7)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 8: Public Health and Clinical Data Registry Reporting

In the Stage 3 proposed rule (80 FR 16763) we proposed this objective to build on the requirements set forth in the Stage 2 final rule (77 FR 54021 through 54026). We proposed this objective to include improvements to the Stage 2 measures, support innovation that has occurred since the Stage 2 final rule was released, and add

flexibility in the options that an eligible provider has to successfully report.

We further noted that this objective places increased focus on the importance of the ongoing lines of communication that should exist between providers and public health agencies or as further discussed later in this section, between providers and clinical data registries. Providers' use of certified EHR technology can increase the flow of secure health information and reduce the burden that otherwise could attach to these important communications. The purpose of this Stage 3 objective is to further advance communication between providers and public health agencies and clinical data registries, as well as strengthen the capture and transmission of such health information within the care continuum.

For Stage 3, we proposed changes to the Stage 1 and Stage 2 public health and specialty registry objectives to consolidate the prior objectives and measures into a single objective in alignment with efforts to streamline the program and support flexibility for providers. We proposed to include a new measure for electronic case reporting to reflect the diverse ways that providers can electronically exchange data with public health agencies. In addition, we used new terms such as public health registries and clinical data registries to incorporate the Stage 2 designations for cancer registries and specialized registries under these categories which are known in the health care industry to designate a broader range of registry types. We further explained the use of these terms within the specifications outlined for each applicable measure.

Proposed Objective: The EP, eligible hospital, or CAH is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

For Stage 3, we proposed to remove the prior "ongoing submission" requirement and replace it with an "active engagement" requirement. Depending on the measure, the ongoing submission requirement from the Stage 1 and Stage 2 final rules required the successful ongoing submission of applicable data from certified EHR technology to a public health agency or clinical data registry for the entire EHR reporting period. As part of the Stage 2 final rule, we provided examples demonstrating how ongoing submission could satisfy the measure (77 FR 54021). However, stakeholders noted that the

ongoing submission requirement does not accurately capture the nature of communication between providers and a public health agency or clinical data registry, and does not consider the many steps necessary to arrange for registry submission to a public health agency or clinical data registry. Given this feedback, we believe that “active engagement” as defined later in this section is more aligned with the process providers undertake to report to a clinical data registry or to a public health agency.

For purposes of meeting this new objective, EPs, eligible hospitals and CAHs would be required to demonstrate that “active engagement” with a public health agency or clinical data registry has occurred. Active engagement means that the provider is in the process of moving towards sending “production data” to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry. We noted that the term “production data” refers to data generated through clinical processes involving patient care and it is used to distinguish between this data and “test, data” which may be submitted for the purposes of enrolling in and testing electronic data transfers. We proposed that “active engagement” may be demonstrated by any of the following options:

Active Engagement Option 1—Completed Registration to Submit Data: The EP, eligible hospital, or CAH registered to submit data with the public health agency or, where applicable, the clinical data registry to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, eligible hospital, or CAH is awaiting an invitation from the public health agency or clinical data registry to begin testing and validation. This option allows providers to meet the measure when the public health agency or the clinical data registry has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Active Engagement Option 2—Testing and Validation: The EP, eligible hospital, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the public health agency or, where applicable, the clinical data registry within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

Active Engagement Option 3—Production: The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the public health agency or clinical data registry.

We also proposed to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local public health agency and clinical data registry readiness. In the Stage 2 final rule (77 FR 54021), we noted the benefits of developing a centralized repository where a public health agency could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objectives. In accordance with the Paperwork Reduction Act of 1995, we also published a notice in the **Federal Register** on February 7, 2014 soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). We considered the comments and we proposed moving forward with the development of the centralized repository. The centralized repository is integral to meaningful use and is expected to be available by the start of CY 2017. We expect that the centralized repository will include readiness updates for public health agencies and clinical data registries at the state, local, and national level. We received the following comments and our responses follow:

Comment: Some commenters expressed concern regarding the active engagement requirement included in the proposed rule. Commenters noted that the description of active engagement is vague. Commenters also noted that additional time, beyond the 2018 requirement year, would be needed to ensure that providers could change their current framework to meet the new active engagement requirement. Other commenters requested clarification on the definition of production in Option 3. Other commenters noted that during the production phase, issues may arise that need resolution and that, similar to the testing and validation phases, processes are needed to ensure proper resolution. A commenter proposed adding a 30-day allowance to the active engagement option 3 (production) to align with the 30-day allowance included in active engagement option 2 (testing and validation).

Response: We thank the commenters for their input and note the following clarifications of intent and purpose for the change from “ongoing submission”

to “active engagement.” We received feedback from a variety of stakeholders that the “ongoing submission” structure created confusion. This feedback highlighted that providers are unsure of how ongoing submission could be achieved and whether periodic, continuous, or episodic reporting was generally required. We found that the wide variation among potential provider reporting scenarios and submission processes contributed to the difficulty in defining “ongoing submission” in a fair and universally applicable manner. Therefore our change to “active engagement” is intended to more clearly identify the progression of the requirement as well as providing a basis for defining the actions required by the provider in each step of the process. In a sense, the active engagement options are a clarification of the more basic concept of reporting which is that the provider is taking action and in communication with a public health agency in order to register, test and submit data in a progression which results in the provider successfully reporting relevant data to the public health agency.

The active engagement requirement clarifies what is expected of a provider who seeks to meet the measures within this objective and renames the requirement to better describe the provider’s role in meeting each option within the structure. There is an intentional similarity between some of the broad descriptions of the Stage 2 “ongoing reporting” and the requirements for the “active engagement” options. This is both to provide continuity and to define a more comprehensive progression for providers in meeting the measure. For example, in the Stage 2 rule (77 FR 54021), we generally stated that a provider could register their intent to submit data to successfully meet a measure in the public health objective. This concept is defined with additional guidance in the Stage 3 proposed rule as Active Engagement Option 1: Completed Registration to Submit Data.

For the commenters discussing the submission of production data as defined in Active Engagement Option 3: Production, we note that under this option a provider only may successfully attest to meaningful use when the receiving public health agency or clinical data registry moves the provider into a production phase. We recognize that live data may be sent during the Testing and Validation phase of Option 2, but the data received in Option 2 is not sufficient for purposes of meeting Option 3 unless the public health agency and clinical data registry is

actively accepting the production data from the provider for purpose of reporting. We agree with commenters who noted that issues may arise that require provider action. In such a case, we require providers to respond to issues in the same manner as described in Option 2. For example, a provider in the production phase would not be able to successfully attest to Option 3 if there were issues in production where the provider fails to respond to an issue within 30 days on two occasions.

Comment: Some commenters sought clarification on whether a provider who has already registered with a public health agency or clinical data registry during a previous reporting period would have to register again in order to meet the active engagement requirement. Commenters noted that a registration requirement in such circumstances would be duplicative.

Response: As we have noted in the proposed rule, under the active engagement requirement, providers would only need to register once with a public health agency or a clinical data registry and could register before the reporting period begins. In addition, we note that previous registrations with a public health agency or clinical data registry that occurred in a previous stage of meaningful use could count toward option 1 of the active engagement requirement for purposes of attesting to Stage 3. We clarify that providers must register with a public health agency or clinical data registry for each measure they intend to use to meet meaningful use. Further, we also clarify that to meet option 1 of the active engagement requirement, registration with the applicable public health agency or clinical data registry is required where a provider seeks to meet meaningful use using a measure they have not successfully attested to in a previous EHR reporting period.

Comment: Commenters requested clarification regarding whether a provider can successfully attest to meaningful use using proof of active

engagement collected by their organization, or whether a provider must demonstrate that he or she independently engaged with the public health agency or clinical data registry.

Response: The EHR Incentive Programs are based on individual providers meeting the objectives and measures of meaningful use. Therefore an individual provider can only meet an objective or measure if they are engaged in the activity which is used to meet the measure. This means a provider can demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the provider directly for individual reporting. Or, a provider also may demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the practice or organization of the provider if the organization reports at the group level as long as the provider is contributing to the data reported by the group. If the provider does not contribute to the data, they must claim the exclusion if applicable and/or meet another public health reporting measure. For example, a provider who does not administer immunizations should claim the exclusion even if their organization submits immunization reporting at the group level.

Comment: Commenters also expressed support for the proposed centralized repository of public health agencies and clinical data registry readiness. Commenters noted that the repository would help developers and providers consider available registry options and provide advance notice of the status of registries. Though the repository received many positive comments, some commenters noted that variability in the readiness of public health agencies presented an additional challenge for providers who seek to prepare for and meet the measures.

Response: In response to comments received and the concern that providers

need advance readiness notification from public health agencies and clinical data registries to prepare and plan before the EHR reporting period begins, we are broadening the exclusions that could apply to providers seeking to meet the objective. The exclusion will allow providers more time to prepare their processes to align with what data public health jurisdictions are ready to accept. Specifically, we will not finalize the proposed requirement that public health agency and clinical data registries declare readiness on the first day of the EHR reporting period. We are instead finalizing a modified exclusion that if public health agencies have not declared 6 months before the start of the EHR reporting period whether the registry they are offering will be ready on January 1 of the upcoming year for use by providers seeking to meet EHR reporting periods in that upcoming year, a provider can claim an exclusion. We believe that modifying the exclusion to request public health agency or clinical data registry to declare their readiness 6 months ahead of the first day of the EHR reporting period would allow providers adequate notice of public health agency and clinical data registry plans to accept data at the beginning of an EHR reporting period.

Proposed Measures: We proposed a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. The proposed measures are as shown in Table 9. As noted, we proposed that measures four and five for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public Health Registry or Clinical Data Registry is available.

TABLE 9—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting	1	1
Measure 2—Syndromic Surveillance Reporting	1	1
Measure 3—Case Reporting	1	1
Measure 4—Public Health Registry Reporting*	3	4
Measure 5—Clinical Data Registry Reporting**	3	4

TABLE 9—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE—
Continued

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 6—Electronic Reportable Laboratory Results	N/A	1

* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.

** EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

For EPs, we proposed that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective, an EP would need to meet three of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than three, the EP can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we proposed that an exclusion for a measure does not count toward the total of four measures. Instead, in order to meet this objective an eligible hospital or CAH would need to meet four of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than four, the eligible hospital or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

We also proposed to allow EPs, eligible hospitals, and CAHs to choose to report to more than one public health registry to meet the number of measures required to meet the objective. We also proposed allowing EPs, eligible hospitals, and CAHs to choose to report to more than one clinical data registry to meet the number of measures required to meet the objective. We explained that we believe that this flexibility allows for EPs, eligible hospitals, and CAHs to choose reporting options that align with their practice and that will aid the provider's ability to care for their patients.

Proposed Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active

engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

In the Stage 3 proposed rule (80 FR 16764), we noted that the immunization registry reporting measure remains a priority because the exchange of information between certified EHR technology and immunization registries allows a provider to use the most complete immunization history available to inform decisions about the vaccines a patient may need. Public health agencies and providers also use immunization information for emergency preparedness and to estimate population immunization coverage levels of certain vaccines.

We proposed that to successfully meet the requirements of this measure, bi-directional data exchange between the provider's certified EHR technology and the immunization registry/IIS is required. We understand that many states and local public health jurisdictions are exchanging immunization data bi-directionally with providers, and that the number of states and localities able to support bi-directional exchange continues to increase. In the 2015 Edition proposed rule, ONC proposed to adopt a bi-directional exchange standard for reporting to immunization registries/IIS. We believe this functionality is important for patient safety and improved care because it allows the provider to use the most complete immunization record possible to make decisions on whether a patient needs a vaccine. Immunization registries and health IT systems also are able to provide immunization forecasting functions which can inform discussions between providers and patients on what vaccines they may need in the future and the timeline for the receipt of such immunizations. Therefore, we believe that patients, providers, and the public

health community would benefit from technology that can accommodate bi-directional immunization data exchange. We welcomed comment on this proposal.

Proposed Exclusion for Measure 1: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

Comment: Many comments supported the concept of bi-directional messaging, but some commenters requested additional background on what bi-directionality means for purpose of the measure. Many commenters expressed concern about elements of the bi-directional components of immunization registry reporting, and around jurisdictional variation and the lack of public health readiness to implement bi-directional data exchange. Many commenters expressed concern about public health readiness for bi-directional data exchange, especially during the EHR Incentive Program reporting periods of 2015 through 2017. A commenter expressed concern that immunization registries are not fully prepared to support bi-directional interfaces. Many commenters also expressed concern around accepting the immunization history and forecast from

an IIS when the EHR may already perform that functionality and may have better information to perform the forecasting algorithm. A commenter expressed concern that the forecast info interface could conflict with their system's existing health maintenance functionality.

Response: Bi-directionality, as noted in the applicable implementation guide Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) ("Release 1.5"), provides that certified health IT must be able to receive and display a consolidated immunization history and forecast in addition to sending the immunization record. Some comments noted that certified EHR technology may already perform the forecast and may have better information to perform the forecasting algorithm. For clarification, we note that the provider's technology certified in accordance with the ONC Health IT Certification Program may layer additional information and recommendations on top of the forecast received from the immunization registry. The requirements of CEHRT serve only as a baseline upon which additional capabilities may be built.

Regarding the bi-directionality requirement, we note that we have modified the requirements of bi-directionality for the EHR Incentive Program for 2015 through 2017 (see section II.B.2.a.x). However, for Stage 3, we believe that the bi-directionality requirement should remain. We believe that by the time Stage 3 begins, the bi-directional components of immunization registry reporting will be ready. At the time of publication of this final rule with comment period, more than half of public health jurisdictions can support bi-directional messaging and the remaining public health jurisdictions are on their way to supporting the bi-directional capability. Therefore, we are finalizing this measure, with the modification that a provider's health IT system may layer additional information on the immunization history, forecast, and still successfully meet this measure.

Proposed Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).

In the Stage 3 proposed rule (80 FR 16764), we noted that this measure remains a policy priority because electronic syndromic surveillance is valuable for early detection of

outbreaks, as well as monitoring disease and condition trends. We distinguished between EPs and eligible hospitals or CAHs reporting locations because, as discussed in the Stage 2 final rule, few public health agencies appeared to have the ability to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically (77 FR 53979). We continued to observe differences in the infrastructure and current environments for supporting electronic syndromic surveillance data submission to public health agencies between eligible hospitals or CAHs and EPs. Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we defined slightly different exclusions for each setting as described later in this section.

Proposed Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

Proposed Exclusion for eligible hospitals/CAHs for Measure 2: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency or urgent care department; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

Comment: Many commenters noted that many jurisdictions are not able to receive ambulatory syndromic surveillance data and that the standards for reporting are vague. A commenter expressed concern that requiring a provider's system to be certified to the ambulatory standard does not provide

value to the industry. Another commenter noted that for the few jurisdictions accepting syndromic surveillance data from ambulatory practices, the data that these jurisdictions are accepting are not data that is commonly considered syndromic surveillance data. A commenter noted that if data is being requested or collected for use cases beyond the standard syndromic surveillance definition, the requested or collected data should be used to report to proposed Measure 4: Public Health Reporting, not this measure.

Response: We agree that few jurisdictions accept syndromic surveillance from non-urgent care eligible professionals and that at times the data that is collected may not be considered traditional syndromic surveillance data. For the EHR Incentive Programs in 2015 through 2017, we continue to offer syndromic surveillance as an option for ambulatory care providers as a few jurisdictions are already accepting such data. Because syndromic surveillance reporting is more appropriate for urgent care settings and eligible hospitals/CAHs, we remove this measure for eligible professionals for Stage 3 with the exception of providers who are practicing in urgent care settings. For CAHs and eligible hospitals, we adopt this measure as proposed. We further note that as any provider for whom reporting is not possible, an exclusion is already available; therefore, the additional setting restriction within the measure language is duplicative and may cause confusion for providers who practice in multiple settings where the measure may have different relevance. We are therefore modifying the measure language and the exclusion to help clarify the measure for those reporting on the measure and the exclusion options for those who are not reporting on the measure.

Proposed Measure 3—Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

This proposed new reporting option was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the public health agency. Public health agencies collect "reportable, conditions", as defined by the state, territorial, and local public health agencies, to monitor disease trends and support the management of outbreaks. In many circumstances, there has been low reporting compliance because providers do not know when, where, or how to report. In some cases,

the time burden to report can also contribute to low reporting compliance. However, electronic case reporting presents a core benefit to public health improvement and a variety of stakeholders identified electronic case reporting as a high value element of patient and continuity of care. Further, we believe that electronic case reporting reduces burdensome paper-based and labor-intensive case reporting. Electronic reporting will support more rapid exchange of case reporting information between public health agencies and providers and can include structured questions or data fields to prompt the provider to supply additional required or care-relevant information.

Proposed Exclusion for Measure 3: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

Comment: For Measure 3, commenters overwhelmingly supported the need for electronic case reporting. Many comments expressed concern with the standards referenced and the immaturity to perform these functions, especially the ability of public health jurisdictions to accept data during the EHR Incentive program for 2015 through 2017. Some commenters noted their support for case reporting, including its potential impact on patient outcomes and the use of data elements for reporting. Another commenter supported the measure, but noted the importance of ensuring high quality data and sufficient funding for public health agencies to accept data transmissions.

Response: We note that we did not finalize the case reporting option for the EHR Incentive Program in 2015 through 2017 to allow additional time for the development of the technology and infrastructure to support the measure. We also, as described elsewhere in this final rule with comment period and as noted in the Stage 2 final rule, we did allow case reporting to continue to

count under the specialized registry measure. For Stage 3, we do believe that case reporting should remain. However, to allow EPs, EHR vendors, and other entities adequate time to prepare for this new measure in Stage 3, this measure will not begin requiring electronic case reporting until 2018. By the 2018 year of Stage 3, we believe that the standards will be mature and that jurisdictions will be able to accept these types of data. Therefore, we finalize this measure as proposed to begin in 2018.

Proposed Measure 4—Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

In the Stage 2 final rule, we were purposefully general in our use of the term “specialized registry” (other than a cancer registry) to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and responses to the February 2014 Public Health Reporting Request for Information, we proposed to carry forward the concept behind this broad category from Stage 2, but also proposed to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We proposed to define a “public health registry” as a registry that is administered by, or on behalf of, a local, state, territorial, or national public health agency and which collects data for public health purposes. While immunization registries are a type of public health registry, we proposed to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023). We believe it is important to retain the public health registry reporting option for Stage 3 because these registries allow the public health community to monitor health and disease trends, and inform the development of programs and policy for population and community health improvement.

We reiterated that any EP, eligible hospital, or CAH may report to more than one public health registry to meet the total number of required measures for the objective. For example, if a provider meets this measure through

reporting to both the National Hospital Care Survey and the National Healthcare Safety Network registry, the provider could get credit for meeting two measures. ONC will consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the public health registry reporting measure through future rulemaking for the EHR Incentive Programs.

We further noted that ONC adopted standards for ambulatory cancer case reporting in its final rule “2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” (79 FR 54468) and we provided EPs the option to select the cancer case reporting menu objective in the Stage 2 final rule (77 FR 54029 through 54030). We included cancer registry reporting as a separate objective from specialized registry reporting because it was more mature in its development than other registry types, not because other reporting was intended to be excluded from meaningful use. For the Stage 3 public health registry reporting measure, given the desire to provide more flexible options for providers to report to the registries most applicable for their scope of practice, we proposed that EPs would have the option of counting cancer case reporting under the public health registry reporting measure. We noted that cancer case reporting is not an option for eligible hospitals and CAHs under this measure because hospitals have traditionally diagnosed or treated cancers and have the infrastructure needed to report cancer cases.

Proposed Exclusions for Measure 4: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Comment: Many commenters noted their support for public health registries. Commenters appreciated the flexibility and additional means to meet the measure, which they noted, aids specialists. Nearly all commenters expressed specific support for the Centralized Readiness Repository noting that it is essential for providers to determine if they can attest to the measure if they should take an exclusion. Commenters also noted the specific content that should be available within the Centralized Readiness Repository.

Response: We appreciate the overall support for this measure. We agree that this measure offers flexibility for specialists and as other public health registry standards mature, additional options will be available. We also appreciate the support for the Centralized Readiness Repository and will make note of the specific requirements made by commenters, including the requirement for national as well as local and state public health registries.

Comment: Some commenters noted that there were no public health registries available for their specialty or that their state may not be ready to receive data for the registries appropriate for them. Commenters were concerned that they would not be able to meet this measure because of a lack of public health registries available to them.

Response: We appreciate the comments. We note that providers may exclude from the public health registry as noted in the exclusions if there are no public health registries available. Providers can still meet the overall objective by choosing other measures or excluding out of other measures.

Comment: Many commenters noted that public health would not be providing data back as part of the public health registries.

Response: We appreciate the comments on the bi-directional component of public health registries. We encourage associations to work with their public health colleagues to maximize the use of data flowing into, and out of, public health registries.

Comment: Many commenters expressed concern that under the proposal, specialized registries included in the Stage 2 final rule would not be available as a measure option for eligible providers seeking to attest to Stage 3. A commenter noted that the addition of specific standards for reporting to public health registries and clinical data registries is a change from the specialized registry objective in Stage 2 and may pose a problem for

states that already designated specialized registries in Stage 2. Another commenter expressed concern that without a special provision in place in Stage 3, some of the existing specialized registries would not meet the requirements for Stage 3.

Response: We understand the concerns raised by these providers. The specialized registry provision included in the Stage 2 final rule was developed to provide additional flexibility to providers to choose a registry best suited for their practice. Many public health jurisdictions began to accept electronic case reporting and prescription drug monitoring during previous stages of meaningful use and these reporting options were considered specialized registries. We want to continue to encourage those providers who have already started down the path of reporting to a specialized registry as part of their participation in Stage 2. Therefore, we will allow such specialized registries to be counted for purposes of reporting to this objective in Stage 3 under the public health registry reporting measure for Stage 3 in 2017, 2018 and subsequent years in the following manner: A provider may count a specialized registry if the provider achieved the phase of active engagement defined under Active Engagement Option 3: Production, including production data submission with the specialized registry in a prior year under the applicable requirements of the EHR Incentive Programs in 2015 through 2017. We do note that reporting to specialized registries does not require certification under the ONC Health IT Certification Program or adherence to specific implementation guides for reporting in 2015 through 2017, and we direct readers to section aI.B.2.b.x for further information on the Specialized Registry Reporting measure for 2015 through 2017.

However we note that providers would not be able to count production reporting to a specialized registry under the Public Health Reporting Objective for 2015 through 2017, if there are standards and requirements referenced in the ONC 2015 Edition regulations for Public Health and Clinical Data Registry Stage 3 Measures:

- Example 1, EPs would not receive credit for cancer reporting under the Specialized Registry measure in Stage 3; rather the EPs would need to be in active engagement with the public health agency under the Public Health Registry Measure to submit cancer case data to the PHA using the standards mandated in the 2015 Edition Certification Criteria.

- Example 2, EPs would not receive credit for case reporting under the Specialized Registry measure in Stage 3 for production data submission that started in Modified Stage 2; rather the EPs would need to be in active engagement with the public health agency under the Case Reporting Measure using the standards mandated in the 2015 Edition Certification Criteria.

In future years, as standards are developed and referenced in future ONC regulations, CMS may require further specialized registries to meet these future requirements under the ONC Health IT Certification Program.

Proposed Measure 5—Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

As discussed in the Public Health Registry Reporting measure, in the Stage 3 proposed rule (80 FR 16766) we proposed to split specialized registry reporting into two separate, clearly defined measures: Public health registry reporting and clinical data registry reporting. In Stage 2 for EPs, reporting to specialized registries is a menu objective and this menu objective includes reporting to clinical data registries. For Stage 3, we proposed to include clinical data registry reporting as an independent measure. The National Quality Registry Network defines clinical data registries as those that record information about the health status of patients and the health care they receive over varying periods of time.²⁰ We proposed to further differentiate between clinical data registries and public health registries as follows: For the purposes of meaningful use, “public health registries” are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and “clinical data registries” are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by public health agencies but that are important to a specialist’s provision of care. Clinical data registries can also be used to monitor health care quality and resource use.

In the Stage 3 proposed rule, we reiterated that any EP, eligible hospital,

²⁰ <https://download.ama-assn.org/resources/doc/cqi/x-pub/nqnm-what-is-clinical-data-registry.pdf>.

or CAH may report to more than one clinical data registry to meet the total number of required measures for this objective. We further noted that ONC will consider the adoption of standards and implementation guides in future rulemaking and should these be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the clinical data registry reporting measure through future rulemaking for the EHR Incentive Programs.

Proposed Exclusions for Measure 5: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Comment: Many commenters noted their support for clinical data registries. Commenters appreciated the flexibility and additional means to meet the measure, which they noted aids specialists. Nearly all commenters expressed specific support for the Centralized Readiness Repository noting that it is essential for providers to determine if they can attest to the measure or if they should take an exclusion. Commenters also noted the specific content that should be available within the Centralized Readiness Repository.

Response: We appreciate the overall support for this measure. We agree that this measure offers flexibility for specialists and as other clinical data registry standards mature, additional options will be available. We also appreciate the support for the Centralized Readiness Repository and will make note of the specific requirements made by commenters, including the requirement for national as well as local and state public health registries.

Comment: A commenter noted that since an increasing number of clinical data registries are national in scope and are essentially “borderless,” it is unclear how CMS would define a provider’s “jurisdiction.”

Response: Our definition of jurisdiction here is general, and the scope may be local, state, regional or at the national level. The definition will be dependent on the type of registry to which the provider is reporting. A registry that is “borderless” would be considered a registry at the national level and would be included for purposes of this measure.

Comment: Some commenters noted that there were no clinical data registries available for the specialty or that their state may not be ready to receive data for the registries appropriate for them. Commenters were concerned that they would not be able to meet this measure because of a lack of clinical data registries available to them.

Response: We appreciate the comments. We note that providers may exclude from the clinical data registry as noted in the exclusions; if there are no clinical data registries available, providers can exclude from this measure. Providers can still meet the overall objective by choosing other measures or excluding out of other measures.

Comment: Many comments noted that organizations hosting clinical data registries would not be providing data back as part of the measure.

Response: We appreciate the comments on the bi-directional component of clinical data registries. We encourage all stakeholders to work with their clinical data registry colleagues to maximize the use of data flowing into, and out of, clinical data registries.

Comment: Many commenters noted that better exclusion criteria should exist for providers in jurisdictions with limited options for reporting and in cases where registries are not able to receive data. A commenter suggested that CMS consider allowing exclusions for providers in states where electronic reporting is not possible. Other commenters noted that specialists and other providers who do not perform specific types of reporting should have better ways to exclude out of the applicable measures. Another commenter noted that for orthopedic surgeons, there are few clinical data registry reporting options.

Response: We believe that the measure and associated exclusions that we have proposed provide a variety of options for providers to successfully attest or as appropriate be excluded from the measure. We note that the measure framework allows for multiple ways to achieve successful attestation under this objective, and allow for a provider to find a reporting option that

works for them. For example, the public health agency and clinical data registry measure does not limit the provider to a predetermined list of reporting options. Rather, these two measures allow a provider to consider a broad array of reporting options available from public health agencies and clinical data registries and allows for reporting options developed in the future to be used to meet this measure. Considering the multiple ways and the flexibility included in this objective, we do not believe that additional exclusions are necessary. We believe that the requirements for exclusions under this objective strike the right balance to ensure that a provider seeking to exclude from a measure is unable to meet the requirements of the measure.

Proposed Measure 6—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to eligible hospitals and CAHs only. Electronic reportable laboratory result reporting to public health agencies is required for eligible hospitals and CAHs in Stage 2 (77 FR 54021). We proposed to retain this measure for Stage 3 to promote the exchange of laboratory results between eligible hospitals/CAHs and public health agencies for improved timeliness, reduction of manual data entry errors, and more complete information.

Proposed Exclusion for Measure 6: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH at the start of the EHR reporting period.

Comment: For Measure 6, Electronic Reportable Laboratory Result Reporting, commenters agreed with the continuation of this measure, but requested that it also be included as an option for EPs with in-house laboratories.

Response: We thank commenters for their support of this measure. However, we do not agree that this measure should be extended to EPs. We note that

in-house laboratories of EPs do not typically perform the types of tests that are reportable to public health jurisdictions. For example, many in-house laboratories focus on tests such as rapid strep tests that test for strep throat. The rapid strep tests are not reportable to public health agencies.

Use of CEHRT for Public Health and Clinical Data Registry Reporting Objective

As proposed previously, the Public Health and Clinical Data Registry Reporting objective requires active engagement with a public health agency to submit electronic public health data from certified EHR technology. ONC defined the standards and certification criteria to meet the definition of CEHRT in its 2011, 2014, and 2014 Release 2 Edition EHR certification criteria rules (see section II.B. of the “2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” for a full description of ONC’s regulatory history (79 FR 54434)). For example, ONC adopted standards for immunization reporting (see § 170.314(f)(1) and (f)(2)), inpatient syndromic surveillance (see § 170.314(f)(3) and (f)(7)), ELR (see § 170.314(f)(4)), and cancer case reporting (see § 170.314(f)(5) and (f)(6)) in its 2014 Edition final rule.

We support ONC’s intent to promote standardized and interoperable exchange of public health data across the country. Therefore, to meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we proposed to define it under § 495.4 in the proposed rule and use the standards included in the 2015 Edition proposed rule. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rulemaking.

Comment: Many commenters requested clarification of the CEHRT specifications for each measure.

Response: We thank the commenters for these comments and refer readers to section II.B.3 for a discussion of the definition of CEHRT and a table referencing the certification criteria required for each objective and measure

for use in 2015 through 2017 and for Stage 3 in 2017, 2018 and subsequent years.

After consideration of public comment received, we are finalizing the objectives, measures, and exclusions as proposed except for the items previously discussed in this section. Specifically we are adopting modifications to include the 6 month lead time for the declaration of readiness for all exclusions for all 6 measures, to clarify the setting specificity for syndromic surveillance reporting, and to specify electronic case reporting. We are finalizing a total of 6 measures for this objective, and EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of two measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. We are finalizing that providers may attest to measure 4 and measure 5 more than once, and that an exclusion to a measure does not count toward the total in the manner proposed. The final objective and measures are as follows:

Objective 8: Public Health and Clinical Data Registry Reporting

Objective: The EP, eligible hospital, or CAH is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

Exclusion for Measure 1: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction’s immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR

reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction’s syndromic surveillance system; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs as of 6 months prior to the start of the EHR reporting period.

Exclusion for eligible hospitals/CAHs for Measure 2: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency or urgent care department; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

Measure 3—Electronic Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

Exclusion for Measure 3: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction’s reportable disease system during the EHR reporting period; (2) operates in a

jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

Measure 4—Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

Exclusions for Measure 4: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive

electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

Measure 5—Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

Proposed Exclusions for Measure 5: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

Measure 6—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

Exclusion for Measure 6: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

We are adopting Objective 8: Public Health and Clinical Data Registry Reporting at § 495.24(d)(8)(i) for EPs and § 495.24(d)(8)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

TABLE 10—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting	1	1
Measure 2—Syndromic Surveillance Reporting	1	1
Measure 3—Case Reporting	1	1
Measure 4—Public Health Registry Reporting*	2	4
Measure 5—Clinical Data Registry Reporting**	2	4
Measure 6—Electronic Reportable Laboratory Results	N/A	1

* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective. A specialized registry to which the EP, eligible hospital or CAH reported using Active Engagement Option 3: Production in a prior year under the EHR Incentive Programs in 2015 through 2017 public health reporting objective may also count toward the measure in 2017, 2018 and subsequent years.

** EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

3. Certified EHR Technology (CEHRT) Requirements

a. CEHRT Definition for the EHR Incentive Programs

The definition of CEHRT establishes the requirements for EHR technology that must be used by providers to meet the meaningful use objectives and

measures. The Stage 2 final rule requires that CEHRT must be used by EPs, eligible hospitals, and CAHs to satisfy their CQM reporting requirements in the Medicare and Medicaid EHR Incentive Programs. In addition, the CQM data reported to CMS must originate from EHR technology that is certified to “capture and export” in accordance

with 45 CFR 170.314(c)(1) and “electronic submission” in accordance with 45 CFR 170.314(c)(3) (77 FR 54053). Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4 and previously referenced ONC’s definition of CEHRT in 45 CFR 170.102.

In the Stage 3 proposed rule 80 FR 16767, rather than establishing a specific CEHRT definition for the EHR Incentive Programs in the 2015 Edition proposed rule, we instead proposed to define the term “Certified EHR Technology” at § 495.4. This proposed change is designed to simplify the overall regulatory relationship between ONC and CMS rules for stakeholders and to ensure that relevant CMS policy for the Medicare and Medicaid EHR Incentive Programs is clearly defined in CMS regulations.

We also proposed that providers must use EHR technology certified at least to the 2014 Edition in 2016 and 2017. We further proposed that providers may adopt EHR technology certified to the 2015 Edition prior to the beginning of Stage 3 in 2017 or 2018, and that technology could be used to satisfy the definition of CEHRT under § 495.4 to demonstrate meaningful use (80 FR 16767 through 16768).

Comment: Some commenters suggested potential changes to the certification program. Some commenters suggested the current EHR incentive programs mandate the use of certified EHRs that incorporate draft standards to support program requirements, including the exchange of health information among clinicians and the format of the content exchanged. Inconsistency in the implementation of the standards by vendors has led to confusion and limited provider success in meeting regulatory requirements for information exchange. For example, Stage 2 of meaningful use established a reliance on the “direct protocol,” a new standard to support the sharing of information. As a result of inconsistent implementation among EHR vendors, the ability to use the direct protocol standard to enable information exchange varies. For example, providers are required to use the C–CDA standard to send patient care summaries in a structured template. However, the C–CDA has proved difficult to use and has not met clinical needs to share pertinent information to support care. Finally, one commenter stated that given the complexity of the objectives proposed under Stage 3, we believe meaningful use of EHRs can only be achieved if and when data captured in various EHRs and other data systems are interoperable.

Response: We refer commenters to the ONC 2015 Edition certification criteria final rule published elsewhere in this **Federal Register** for the established standards for certified health IT (see also the 2015 Edition proposed rule at 80 FR 16813 through 16872). We note that in the Stage 2 rule we adopted

multiple options for HIE transport, and in this final rule with comment period, we have further expanded the mechanisms by which a provider can send and receive a C–CDA. We maintain that the C–CDA standard is required, and that a single C–CDA standard serves to support the interoperable exchange of health information.

Comment: Many commenters supported the proposal to allow providers to upgrade to the 2015 Edition at their own pace with an allowance for early upgrades in 2016 and 2017. Commenters noted that with the modular certification process, providers may be able to update parts of systems beginning in late 2016 so the allowance for technology certified to a combination of Editions is necessary. Most commenters noted that, given the timing, it is unlikely that technology certified to the 2015 Edition will be widely available in time to participate in Stage 3 in 2017 and expressed support of the flexibility to select a stage in 2017. Other commenters expressed concern citing the same reasons and noted that the time between publication and implementation of the requirements of the Stage 3 final rule is too short to require 2015 Edition and Stage 3 in 2017. Some commenters suggested that 18 months is required for the transition and suggested making Stage 3 optional in 2018 or further delaying Stage 3 to support the upgrade timing.

Response: We thank the commenters for their input and agree that the shift should allow for greater flexibility in the upgrade process for developers and providers. We note that we have changed the EHR reporting period in 2017 to 90 days for providers who choose to participate in Stage 3, which allows a longer time frame between the publication of the final rules and implementation of systems capable of supporting the Stage 3 objectives and measures. We also note that many of the standards required for Stage 3 are similar or the same in 2014 and 2015 Edition certification criteria. Finally, we reiterate the requirement that providers use the 2015 Edition in 2018 to meet the requirements for Stage 3 for an EHR reporting period in 2018 and note that this timing also allows more than 24 months to the requirement to use technology certified to the 2015 Edition for an EHR reporting period in 2018.

Comment: Some commenters expressed support for our decision to move the CEHRT definition from the ONC certification criteria rules to the EHR Incentive Programs rule. Other commenters expressed concern regarding whether moving the CEHRT definition to the Stage 3 rule would

increase confusion. A commenter noted that the Stage 3 proposed rule reference to “certified EHR technology” conflicts with use of the term “health information technology” in the 2015 Edition proposed rule.

Several commenters addressed proposals specific to the Health IT Certification Program, the scope and focus of the certification criteria and standards for health IT under consideration by the ONC, testing of health IT systems presented for certification to ONC, and the specifics on how the newly created interoperability standards apply to the certification process.

Response: CMS, in consultation with ONC, believes that placing the CEHRT definition in the Stage 3 rule increases the simplicity of the rule. We do not believe that moving the CEHRT definition will lead to program confusion. Rather, by placing the requirements of the CEHRT definition within the rule that it impacts—the Stage 3 rule—we avoid confusion regarding the scope of the CEHRT definition (which is limited to EHR Incentive Program participants) and the broader scope of the ONC Health IT Certification Program (which applies to EHR Incentive Program participants and others, and may be used by other HHS programs). We believe that placing the CEHRT definition within the Stage 3 rule is appropriate and CMS will continue to work closely with ONC on the certification requirements that would be needed to support the objectives and measures of the EHR Incentive Programs. In addition, we are committed to releasing educational materials that will ease the transition related to the move of the CEHRT definition and, as requested by many commenters, have included a chart that outlines the certification criteria that will support providers who intend to attest to Stage 3 of meaningful use.

Regarding references in to “health IT,” we do not agree that the use of the term “health IT” and the use of the term “certified EHR technology” is evidence of a disconnect between the Stage 3 and the ONC Health IT Certification Program. Rather, certified EHR technology is one type of health IT and is mandated required by the HITECH Act as part of for purposes of meeting attestation requirements and becoming a meaningful user. The ONC Health IT Certification Program and the associated 2015 Edition final rule provides certification criteria and standards integral to the CEHRT definition for Stage 3, but also is designed to address the needs of a broader set of settings that

use health IT functionality beyond the requirements of the CEHRT definition.

Finally, comments related to the specific certification criteria proposed in the 2015 Edition proposed rule are outside the scope of this rulemaking. We direct commenters to the 2015 Edition proposed rule published on March 30, 2015. (80 FR 16804 through 16921) and the 2015 Edition final rule published elsewhere in this **Federal Register**.

After consideration of public comments received, we are finalizing the provision to include a full EHR Incentive Programs specific definition of CEHRT at 495.4 as proposed.

b. Defining CEHRT for 2015 Through 2017

In adopting a CEHRT definition specific for the EHR Incentive Programs, we proposed in the EHR Incentive Programs in the Stage 3 proposed rule 80 FR 16767 to include, as currently for the ONC CEHRT definition under 45 CFR 170.102, the relevant Base EHR definitions adopted by ONC in 45 CFR 170.102 and other ONC certification criteria relevant to the EHR Incentive Programs. We referred readers to ONC's 2015 Edition proposed rule for the proposed 2015 Edition Base EHR definition and a discussion of the 2014 Edition Base EHR definition. We included the Base EHR definition(s) because, as ONC explained in the 2014 Edition certification final rule (77 FR 54443 through 54444), the "Base EHR" essentially serves as a substitute for the term "Qualified EHR" in the definition of CEHRT. The term "Qualified EHR" is defined in section 3000(13) of the Public Health Service Act (PHSA), to include certain capabilities listed in that section, and is included in the statutory definition of "certified EHR technology" for the EHR Incentive Programs (for example, see section 1848(o)(4) of the Act). The Base EHR definition(s) also includes additional capabilities as proposed by ONC that we agreed all providers should have that are participating in the EHR Incentive Programs to support their attempts to meet meaningful use objectives and measures, as well as to support interoperable health information exchange.

We also proposed to define the editions of certification criteria that may be used for years 2015 through 2017 to meet the CEHRT definition. At a minimum, EPs, eligible hospitals, and CAHs would be required to use EHR technology certified to the 2014 Edition certification criteria for their respective EHR reporting periods in 2015 through 2017. We stated that a provider may also

upgrade to the 2015 Edition prior to 2018 to meet the required certified EHR technology definition for the EHR reporting periods in 2015, 2016, or 2017, or they may use a combination of 2014 and 2015 Editions prior to 2018 if they have modules from both Editions which that meet the requirements for the objectives and measures or if they fully upgrade during an EHR reporting period.

Additionally, because ONC proposed, for the 2015 Edition, to no longer require certification of Health IT Modules to capabilities that support meaningful use objectives with percentage-based measures, we proposed to include these capabilities (45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2)), as applicable, in the CEHRT definition for 2015 through 2017, so that providers have technology that can appropriately record and calculate meaningful use measures. In the EHR Incentive Program in the Stage 3 proposed rule, we noted that there are many combinations of 2014 and 2015 Edition certified technologies that could be used to successfully meet the transitions of care requirements included in the 2014 and 2015 Edition Base EHR definitions for the purposes of meeting meaningful use objectives and measures. We explained that we believe we have identified all combinations in the proposed regulation text under § 495.4 that could be used to meet the CEHRT definition through 2017 and be used for the purposes of meeting meaningful use objectives and measures. We sought comments on the accuracy of the identified available options. We received the following comments and our responses follow:

Comment: Some commenters expressed concern that there is a misalignment between the requirements of the ONC Health IT Certification Program and the objectives and measures of Stage 3. Specifically, the commenter noted that though the automated numerator recording and measure calculation are not required for a module to be certified to the 2015 Edition, it is required for Stage 3.

Response: The automated numerator recording and measure calculation are not requirements of modules seeking certification under the 2015 Edition final rule. However, this does not represent a misalignment between the ONC Health IT Certification Program and the EHR Incentive Programs. Rather, the two criteria are required for purposes of meeting meaningful use, but may not be necessary for other users of the ONC's Health IT Certification Program. For example, a non-EHR Incentive Program provider using

technology certified by the ONC Health IT Certification Program to meet requirements of CMS' chronic care management program would not need the automated numerator recording and measure calculation. ONC has sought to avoid requiring non-EHR Incentive Program participants to possess technology with the criteria previously stated in this final rule with comment period. Therefore, the 2015 Edition proposed and final rule includes the criteria for developers who intend to certify their products for use by EHR Incentive Program providers, but it does not make such criteria requirements for all technology certified under the ONC Health IT Certification Program.

Comment: Some commenters requested clarification on whether 2014 Edition or 2015 Edition (or both) could be used to attest to meaningful use in 2015 through 2017.

Response: We clarify as follows:

For EHR reporting periods in 2017:

- A provider who has technology certified to the 2015 Edition may attest to Stage 3 or to the modified Stage 2 requirements identified elsewhere in this rule.
- A provider who has technology certified to a combination of 2015 Edition and 2014 Edition may attest to: (1) The modified Stage 2 requirements; or (2) potentially to the Stage 3 requirements if the mix of certified technologies would not prohibit them from meeting the Stage 3 measures.
- A provider who has technology certified to the 2014 Edition only may attest to the modified Stage 2 requirements and may not attest to Stage 3.

For EHR reporting periods in 2018:

- All providers must use technology certified to the 2015 Edition to meet Stage 3 requirements.

Comment: Commenters expressed concern that it is unclear whether technology that is certified only to the Base EHR definition is adequate for purposes of attesting to meaningful use. Another commenter suggested that the "Base certified EHRs" should be fully capable of meeting the needs of an EHR Incentive Program participant, without having to—for example—purchase add-ons, interfaces, or pay for reporting. Some commenters noted that requiring providers to attest to meaningful use using technology certified to the 2015 Edition Base EHR definition will result in providers having to possess software that is not necessary to that provider achieving meaningful use.

Response: Technology that is certified only to the Base EHR definition would not be adequate for purposes of attesting to meaningful use in any EHR reporting

period. We agree that the components of the Base EHR definition proposed in the 2015 Edition proposed rule are integral to attesting to meaningful use and include a variety of criteria including, among others, criteria related to demographics, CPOE, medication allergy lists and data portability. However, the Base EHR definition does not include criteria related to items such as public health reporting, electronic prescribing, and drug-drug/drug-allergy checks—which also are integral to attest to meaningful use.

The Base EHR definition is designed to include specific criteria that would apply to a broad cross section of developers seeking to support provider needs. The Base EHR definition is not designed solely for the use of the EHR Incentive Programs. For this reason, a product that a provider seeks to use to attest to meaningful use must be certified to the Base EHR definition and additional criteria that is determined by (a) the requirements of this CEHRT definition and (b) the specific objectives and measures the provider intends to use to meet meaningful use. Therefore, we do not believe it is appropriate to limit the CEHRT definition to the criteria included in ONC's Base EHR definition.

In this final rule with comment period, we have specifically identified the privacy and security certification criteria that EHR technology must be certified to meet the CEHRT definition for any federal fiscal year or calendar year before 2018, when an EP, eligible hospital, or CAH is using EHR certified to both the 2014 Edition and 2015 Edition to meet the definition.

We proposed provisions in the CEHRT definition for any federal fiscal year or calendar year before 2018 that would permit the use of a mix of EHR technology certified to 2014 and 2015 editions. This was designed to account for providers upgrading from EHR technology certified to the 2014 Edition to the 2015 Edition to meet the requirements of the CEHRT definition for 2018 and subsequent years (*i.e.*, the use of EHR technology only certified to the 2015 Edition). In most instances, providers will have certified privacy and security capabilities because these capabilities are part of the 2014 Edition Base EHR definition. The proposal also took into account that the adoption of EHR technology certified to the 2015 Edition would likely include most, if not, all relevant privacy and security capabilities. For example, EHR technology certified only to the 2015 Edition CPOE-order medications criterion will also be required to be certified to the 2015 Edition versions of

all privacy and security criteria included in the 2014 Edition Base EHR definition, except the “integrity” criterion.

Our proposal did not, however, account for the unlikely, but plausible, scenario where a new entrant to the EHR Incentive Programs in 2016 or 2017 was able to meet the CEHRT definition for a federal fiscal year or calendar year before 2018 with EHR technology only or mostly certified to the 2014 Edition that did not include the requisite privacy and security capabilities which are part of the 2014 Base EHR definition. Therefore, we have specifically included privacy and security certification criteria in the definition to guard against this possibility.

We note that we encourage providers to work closely with their developers to determine what compilation of technology certified under the ONC Health IT Certification Program would allow the provider to successfully attest to meaningful use in an EHR reporting period covered under this rule. We also have provided a chart of the technology that would be required for a provider seeking to attest to an objective or measure (See Table 2, 80 FR 16810 through 16811). In addition, we encourage providers to review the Web site of the ONC Health IT Certification Program and the Certified Health IT Products List (CHPL), which include real time information on what products are certified for what functionalities (see www.healthit.gov).

We note that some commenters expressed concern regarding fraudulent statements and claims regarding the technology offered to meet meaningful use. We encourage providers to use the CHPL as a resource for identifying whether a product is certified and to contact ONC if fraudulent activity is suspected.

After consideration of public comments received, we are finalizing and adopting this provision without modification at § 495.4.

c. Defining CEHRT for 2018 and Subsequent Years

In the Stage 3 proposed rule at 80 FR 16767, we proposed that starting with 2018, all EPs, eligible hospitals, and CAHs would be required to use technology certified to the 2015 Edition to meet the CEHRT definition and to demonstrate meaningful use for an EHR reporting period in 2018 and subsequent years. The CEHRT definition would include, for the reasons discussed previously, meeting the 2015 Edition Base EHR definition and having other

important capabilities that include the capabilities to:

- Record or create and incorporate family health history;
- Capture patient health information such as advance directives;
- Record numerators and denominators for meaningful use objectives with percentage-based measures and calculate the percentages;
- Calculate and report clinical quality measures; and
- Any other capabilities needed to be a Meaningful EHR User.

For information on 2015 Edition certification criteria that include these capabilities and are associated with proposed Meaningful Use objectives for Stage 3, we referred readers to the 2015 Edition proposed rule. We noted that we expect that the certification criteria with capabilities that support CQM calculation and reporting would be jointly proposed with CQM reporting requirements in a separate rulemaking.

Comment: We received a variety of comments on these proposals. Some commenters agreed that technology certified to the 2015 Edition would be developed and could be implemented by providers by 2018. Other commenters expressed their concern that requiring providers to attest to Stage 3 using 2015 Edition technology in 2018 was not realistic, and did not account for the new technology that needed to be developed to support the objectives and measures in Stage 3.

Some commenters requested that providers in 2018 be allowed to use technology certified to the 2014 Edition and the 2015 Edition to meet Stage 3 requirements. A commenter expressed a concern that requiring use of 2015 Edition in 2018 may be problematic for certain providers that need radiation oncology EHR products. The commenter requested that the 2018 year be a flex year as well as 2017. Another commenter suggested that making the 2015 Edition optional in 2017 could create confusion and that we should simply adopt a single edition.

Response: We note that 2017 provides a flex year for providers to fully implement their CEHRT. Extending the flex year beyond 2017 would slow provider progression to updated technology that better enables interoperability, care coordination, and health information exchange. We appreciate commenters concerns regarding whether technology certified to the 2015 Edition would be ready in 2018. Developers have noted that between 18 or 24 months is the necessary to develop and implement health IT technology. With the finalization of this final rule with

comment period, developers and providers will have more than 24 months to develop and implement 2015 Edition technology required by this final rule with comment period.

Further, we note that many of the requirements of Stage 3 are similar to those of Stage 2 and would use the same certification criteria with slight updates to vocabulary standards. For those criteria that are new to meaningful use in Stage 3 or for which significant updates are required, we agree with developers who confirm that 18 to 24 months provide enough time to develop and implement certified technology for purposes of meaningful use. We refer readers to section III.A. Table 2 of the ONC 2015 Edition Certification Criteria final rule published elsewhere in this **Federal Register** for further information on the differences between 2014 Edition and 2015 Edition criteria.

We further note that 2018 is the required year for the use of 2015 Edition and for attesting to Stage 3. We proposed and are finalizing in this rule a 2017 flex year that allows providers options in the edition of CEHRT used and the stage of meaningful use to which the provider attests. This flexibility is in place in recognition of the implementation needed for technology. However, by 2018, all providers will be required to attest to Stage 3 using 2015 Edition technology.

Comment: Some commenters requested clarification on if a provider would be required to be certified to technology needed for measures the provider does not intend to use for attestation or if there is a specific certification requirement for certain specialties.

Response: ONC certifies products not by specialty, but by each specific functionality. In some cases, intended inpatient or ambulatory use may be a factor in the product a provider chooses to possess. Beyond this distinction, the definition of CEHRT includes the requirements specific to each measure which may be independently certified and a provider may not be required to obtain and use functions for which they do not intend to attest. We recognize that there are multiple permutations that could lead to a successful attestation under the EHR Incentive Programs. For example, a provider may decide to attest to the modified Stage 2

or Stage 3 Public Health measure using reporting options other than syndromic surveillance reporting. In such a case, the provider would not need to possess technology certified to ONC's "Transmission to Public Health Agencies—Syndromic Surveillance Criterion". In contrast, in Stage 3, some objectives require a provider to attest to all three measures but only successfully meet the thresholds of two of the three measures. For such objectives, a provider would need to possess certified technology for all three measures for purposes of attesting. We further note that in the case of a provider that meets the exclusions of a measure, the provider is not required to possess technology to meet that measure.

We caution providers to carefully make determinations regarding the technology they will need to attest to meaningful use and encourage providers to work closely with their developers to ensure that the technology they possess will meet their attestation needs. Please refer to Tables 11 through 16, which we have developed in conjunction with ONC of the technology requirements that support the CEHRT definition and each measure in section II.B.3.(d) of this final rule with comment period.

We also note that the CEHRT definition provides a baseline of functionality, but a provider may choose to possess technology that goes beyond the requirements of this CEHRT definition. We encourage providers to review products available to meet their needs and to review the Certified Health IT Products List that is available online at www.healthit.gov.

Comment: Some commenters suggested that providers should not be required to possess technology that is certified to record or create and incorporate family health history.

Response: We do not agree. Family health history is an integral component in the provision of care and the criterion supports the intake of such data into a provider's health IT system. As a result, care coordination between providers and between providers and patients is improved and accessible. The CEHRT definition includes the baseline of functionality that we believe is necessary to provide better care, advance care coordination, and support interoperability. Requiring a provider to have a system that is able to capture

family health history or other patient information (such as advanced directives) is a foundational element of health IT that we will continue to support. For this reason, we decline to remove family health history or the requirement to capture patient health information from the CEHRT definition.

Comment: A commenter recommended that the ability to automatically query an HIE and retrieve a summary of care document be part of the definition of CERT. Many current systems rely on an EP to download a summary of care document from an external portal and then manually upload it into their EHR.

Response: This was not a separate functionality that we proposed to be part of the CEHRT definition, and we do not intend to adopt this suggestion as part of the CEHRT definition. However, we did propose that to meet the CEHRT definition a provider must have technology certified to the "Transitions of Care" certification criterion (45 CFR 170.315(b)(1)). The criterion requires that technology be capable of sending and receiving a C-CDA. We believe this will support a provider's ability to electronically exchange interoperable health information.

After consideration of public comments received, we are finalizing and adopting this provision as proposed at § 495.4.

d. Final Definition of CEHRT

To facilitate readers identifying the requirements of CEHRT for each objective and measure defined in sections II.B.2.a and II.B.2.b of this final rule with comment period, ONC and CMS have developed a set of tables providing the appropriate certification criteria reference under the 2014 Edition and 2015 Edition certification criteria for the objectives and measures of meaningful use. These tables are provided for reference purposes and reflect the definition of CEHRT adopted at § 495.4 for each year. We note that providers must also have the capabilities defined at § 495.4 for clinical quality measures (1)(ii)(B) or (2)(ii)(B), privacy and security (1)(ii)(C) or (2), and the certification criteria that are necessary to be a Meaningful EHR User (1)(ii)(D) or (2)(ii)(A).

TABLE 11—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR 2015 THROUGH 2017

Objective	Measure(s)	2014 edition	2015 edition	Additional considerations
Objective 1: Protect Patient Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.	The requirements are included in the Base EHR Definition.	The requirements are a part of CEHRT specific to each certification criterion.	The requirements are a part of CEHRT specific to each certification criterion.
Objective 2: Clinical Decision Support.	<i>Measure 1:</i> Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. <i>Measure 2:</i> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(8) (Clinical Decision Support). § 170.314(a)(2) (Drug-drug, Drug-Allergy Interaction Checks).	§ 170.315(a)(9) (Clinical Decision Support). § 170.315(a)(4) (Drug-drug, Drug-Allergy Interaction Checks for CPOE).	N/A. N/A.
Objective 3: Computerized Provider Order Entry CPOE.	<i>Measure 1:</i> More than 60% of medication orders created by the EP during the EHR reporting period are recorded using CPOE. <i>Measure 2:</i> More than 30% of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE. <i>Measure 3:</i> More than 30% of radiology orders created by the EP during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(18) (Optional—Computerized Provider Order Entry—Medications). § 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(19) (Optional—Computerized Provider Order Entry—Laboratory). § 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(20) (Optional—Computerized Provider Order Entry—Diagnostic Imaging).	§ 170.315(a)(1) (Computerized Provider Order Entry—Medications). § 170.315(a)(2) (Computerized Provider Order Entry—Laboratory). § 170.315(a)(3) (Computerized Provider Order Entry—Diagnostic Imaging).	N/A. N/A. N/A.
Objective 4: Electronic Prescribing.	<i>Measure:</i> More than 50% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing). § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks).	§ 170.315(b)(3) (Electronic Prescribing). § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks).	EPs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.
Objective 5: Health Information Exchange.	<i>Measure:</i> The EP that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10% of transitions of care and referrals.	§ 170.314(b)(2) (Transitions of Care—Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional—Transitions of care).	§ 170.315(b)(1) (Transitions of Care).	N/A.
Objective 6: Patient-Specific Education.	<i>Measure:</i> Patient-specific education resources identified by CEHRT are provided to patients for more than 10% of all unique patients with office visits seen by the EP during the EHR reporting period.	§ 170.314(a)(15) (Patient-Specific Education Resources).	§ 170.315(a)(13) (Patient-Specific Education Resources).	N/A.
Objective 7: Medication Reconciliation.	<i>Measure:</i> The EP performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP.	§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional—Clinical Information Reconciliation and Incorporation).	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).	N/A.
Objective 8: Patient Electronic Access (VDT).	<i>Measure 1:</i> More than 50% of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information.	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).	N/A.

TABLE 11—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR 2015 THROUGH 2017—Continued

Objective	Measure(s)	2014 edition	2015 edition	Additional considerations
	<p><i>Measure 2:</i> For 2015 and 2016: At least one patient seen by the EP during the EHR reporting period (or his or her authorized representatives) views, downloads, or transmits his or her health information to a third party, during the EHR reporting period.</p> <p>For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits their health information to a third party, during the EHR reporting period.</p>	<p>§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).</p>	<p>N/A.</p>
<p>Objective 9: Secure Messaging.</p>	<p><i>Measure:</i> For 2015: During the EHR reporting period the capability for patients to send and receive a secure electronic message with the EP was fully enabled.</p> <p>For 2016: For at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p> <p>For 2017: For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	<p>§ 170.314(e)(3) (Secure Messaging).</p>	<p>§ 170.315(e)(2) (Secure Messaging).</p>	<p>N/A.</p>
<p>Objective 10: Public Health Reporting.</p>	<p><i>Measure 1—Immunization Registry Reporting.</i></p> <p><i>Measure 2—Syndromic Surveillance Reporting.</i></p> <p><i>Measure 3—Specialized Registry Reporting</i></p>	<p>§ 170.314(f)(1) (Immunization Information) and § 170.314(f)(2) (Transmission to Immunization Registries).</p> <p>§ 170.314(f)(3) (Transmission to Public Health Agencies—Syndromic Surveillance) or § 170.314(f)(7) (Optional—Ambulatory Setting Only—Transmission to Public Health Agencies—Syndromic Surveillance).</p> <p>§ 170.314(f)(5) (Optional—Ambulatory Setting Only—Cancer Case Information) and § 170.314(f)(6) (Optional—Ambulatory Setting Only—Transmission to Cancer Registries).</p>	<p>N/A</p> <p>§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance) Urgent Care Settings Only.</p> <p>EPs may choose one or more of the following: § 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting). § 170.315(f)(7) Transmission to Public Health Agencies—Health Care Surveys. § 170.315(f)(4) Transmission to Cancer Registries.</p>	<p>N/A.</p> <p>N/A.</p> <p>Certified EHR technology is not required for specialized registry reporting for 2015–2017, but EHR technology certified to the 2014 Edition or 2015 Edition may be used. Other non-named specialized registries unsupported by certification requirements may also be chosen.</p>

TABLE 12—ELIGIBLE HOSPITAL AND CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR 2015 THROUGH 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Additional considerations
Objective 1: Protect Patient Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the eligible hospital or CAH's risk management process.	The requirements are included in the Base EHR Definition.	The requirements are a part of CEHRT specific to each certification criterion.	The requirements are a part of CEHRT specific to each certification criterion.
Objective 2: Clinical Decision Support.	<i>Measure 1:</i> Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period.	§ 170.314(a)(8) (Clinical Decision Support).	§ 170.315(a)(9) (Clinical Decision Support).	N/A.
	<i>Measure 2:</i> The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(2) (Drug-drug, Drug-Allergy Interaction Checks).	§ 170.315(a)(4) (Drug-drug, Drug-Allergy Interaction Checks for CPOE).	N/A.
Objective 3: Computerized Provider Order Entry CPOE.	<i>Measure 1:</i> More than 60% of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(18) (Optional—Computerized Provider Order Entry—Medications).	§ 170.315(a)(1) (Computerized Provider Order Entry—Medications).	N/A.
	<i>Measure 2:</i> More than 30% of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(19) (Optional—Computerized Provider Order Entry—Laboratory).	§ 170.315(a)(2) (Computerized Provider Order Entry—Laboratory).	N/A.
	<i>Measure 3:</i> More than 30% of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(20) (Optional—Computerized Provider Order Entry—Diagnostic Imaging).	§ 170.315(a)(3) (Computerized Provider Order Entry—Diagnostic Imaging).	N/A.
Objective 4: Electronic Prescribing.	<i>Measure:</i> More than 10% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing). § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks).	§ 170.315(b)(3) (Electronic Prescribing). § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks).	Eligible hospitals and CAHs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.
Objective 5: Health Information Exchange.	<i>Measure:</i> The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10% of transitions of care and referrals.	§ 170.314(b)(2) (Transitions of Care—Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional—Transitions of care).	§ 170.315(b)(1) (Transitions of Care).	N/A.
Objective 6: Patient-Specific Education.	<i>Measure:</i> More than 10% of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient specific education resources identified by CEHRT.	§ 170.314(a)(15) (Patient-Specific Education Resources).	§ 170.315(a)(13) (Patient-Specific Education Resources).	N/A.
Objective 7: Medication Reconciliation.	<i>Measure:</i> The eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional—Clinical Information Reconciliation and Incorporation).	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).	N/A.
Objective 8: Patient Electronic Access (VDT).	<i>Measure 1:</i> More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH are provided timely access to view online, download and transmit their health information to a third party their health information.	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).	N/A.

TABLE 12—ELIGIBLE HOSPITAL AND CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR 2015 THROUGH 2017—Continued

Objective	Measure(s)	2014 Edition	2015 Edition	Additional considerations
	<i>Measure 2:</i> For 2015 and 2016: At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads, or transmits to a third party his or her information during the EHR reporting period. For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) view, download, or transmit to a third party their information during the EHR reporting period.	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).	N/A.
Objective 9: Secure Messaging.	N/A	N/A	N/A	N/A.
Objective 10: Public Health Reporting.	<i>Measure 1—Immunization Registry Reporting.</i>	§ 170.314(f)(1) (Immunization Information) and § 170.314(f)(2) (Transmission to Immunization Registries).	N/A	N/A.
	<i>Measure 2—Syndromic Surveillance Reporting.</i>	§ 170.314(f)(3) (Transmission to Public Health Agencies—Syndromic Surveillance).	§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance).	N/A.
	<i>Measure 3—Specialized Registry Reporting.</i>	N/A	Eligible Hospitals/CAHs may choose one or more of the following: § 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting). § 170.315(f)(6) Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting. § 170.315(f)(7) Transmission to Public Health Agencies—Health Care Surveys.	Certified EHR technology is not required for specialized registry reporting for 2015–2017, but EHR technology certified to the 2014 Edition or 2015 Edition may be used. Other non-named specialized registries unsupported by certification requirements may also be chosen.
	<i>Measure 4—Electronic Reportable Laboratory Result Reporting.</i>	§ 170.314(f)(4) (Inpatient Setting Only—Transmission of Reportable Laboratory Tests and Values/Results).	§ 170.315(f)(3) (Transmission to Public Health Agencies—Reportable Laboratory Tests and Values/Results).	N/A.

TABLE 13—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 1: Protect Electronic Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.	The requirements are included in the Base EHR Definition.	The requirements are a part of CEHRT specific to each certification criterion.	The requirements are a part of CEHRT specific to each certification criterion.
Objective 2: Electronic Prescribing.	<i>Measure:</i> More than 60% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing) § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks).	§ 170.315(b)(3) (Electronic Prescribing). § 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks).	EPs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.
Objective 3: Clinical Decision Support.	<i>Measure 1:</i> The EP must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.	§ 170.314(a)(8) (Clinical Decision Support).	§ 170.315(a)(9) (Clinical Decision Support).	N/A.

TABLE 13—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017—Continued

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 4: Computerized Provider Order Entry (CPOE).	<p><i>Measure 2:</i> The EP has enabled and implemented the functionality for drug—drug and drug—allergy interaction checks for the entire EHR reporting period.</p> <p><i>Measure 1:</i> More than 60% of medication orders created by the EP during the EHR reporting period are recorded using CPOE.</p> <p><i>Measure 2:</i> More than 60% of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE.</p> <p><i>Measure 3:</i> More than 60% of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using CPOE.</p>	<p>§ 170.314(a)(2) (Drug-Drug, Drug-Allergy Interaction Checks).</p> <p>§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(18) (Optional—Computerized Provider Order Entry—Medications).</p> <p>§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(19) (Optional—Computerized Provider Order Entry—Laboratory).</p> <p>§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(20) (Optional—Computerized Provider Order Entry—Diagnostic Imaging).</p>	<p>§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE).</p> <p>§ 170.315(a)(1) (Computerized Provider Order Entry—Medications).</p> <p>§ 170.315(a)(2) (Computerized Provider Order Entry—Laboratory).</p> <p>§ 170.315(a)(3) (Computerized Provider Order Entry—Diagnostic Imaging).</p>	<p>N/A.</p> <p>N/A.</p> <p>N/A.</p> <p>N/A.</p>
Objective 5: Patient Electronic Access.	<p><i>Measure 1:</i> For more than 80% of all unique patients seen by the EP:</p> <p>(1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and</p> <p>(2) The EP ensures the patient's health information is available for the patient (or patient—authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.</p> <p><i>Measure 2:</i> The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients seen by the EP.</p>	<p>§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).</p> <p>§ 170.314(a)(15) (Patient-Specific Education Resources).</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).</p> <p>§ 170.315(g)(7) (Application Access—Patient Selection) *.</p> <p>§ 170.315(g)(8) (Application Access—Data Category Request) *.</p> <p>§ 170.315(g)(9) (Application Access—All Data Request) *.</p> <p>* The three criteria combined are the "API" certification criteria.</p> <p>§ 170.315(a)(13) (Patient-specific Education Resources).</p>	<p>EPs may use technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., § 170.314(e)(1) or § 170.315(e)(1)) in 2017). The 2014 Edition does not offer "API" certification criteria. Therefore, EPs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to § 170.315(g)(7), § 170.315(g)(8), and § 170.315(g)(9).</p> <p>N/A.</p>
Objective 6: Coordination of Care through Patient Engagement.	<p><i>Measure 1:</i> For 2017, during the EHR reporting period, more than 5% of all unique patients (or patient-authorized representative) seen by the EP actively engage with the EHR made accessible by the provider. An EP may meet the measure by either—</p> <p>(1) view, download or transmit to a third party their health information; or</p> <p>(2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2).</p> <p><i>Measure 2:</i> For 2017, more than 5% of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).</p>	<p>§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).</p> <p>§ 170.314(e)(3) (Secure Messaging).</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).</p> <p>§ 170.315(g)(7) (Application Access—Patient Selection) *.</p> <p>§ 170.315(g)(8) (Application Access—Data Category Request) *.</p> <p>§ 170.315(g)(9) (Application Access—All Data Request) *.</p> <p>* The three criteria combined are the "API" certification criteria.</p> <p>§ 170.315(e)(2) (Secure Messaging).</p>	<p>EPs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., § 170.314(e)(1) or § 170.315(e)(1)) in 2017). The 2014 Edition does not offer API certification criteria. Therefore, EPs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to § 170.315(g)(7), § 170.315(g)(8), and § 170.315(g)(9).</p> <p>N/A.</p>

TABLE 13—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017—Continued

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 7: Health Information Exchange.	<i>Measure 3:</i> Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 of all unique patients seen by the EP during the EHR reporting period.	N/A	§ 170.315(e)(3) (Patient Health Information Capture)*. * Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.	
	<i>Measure 1:</i> For more than 50% of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.	§ 170.314(b)(2) (Transitions of Care—Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional—Transitions of Care).	§ 170.315(b)(1) (Transitions of Care).	N/A.
	<i>Measure 2:</i> For more than 40% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP receives or retrieves and incorporates into the patient's record an electronic summary of care document. <i>Measure 3:</i> For more than 80% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP performs clinical information reconciliation.	§ 170.314(b)(1) (Transitions of Care-Receive, Display and Incorporate Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional—Transitions of Care). § 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional—Clinical Information Reconciliation and Incorporation).	§ 170.315(b)(1) (Transitions of Care). § 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).	N/A. N/A.
Objective 8: Public Health and Clinical Data Registry Reporting. Data Registry Reporting	<i>Measure 1:</i> Immunization Registry Reporting.	N/A	§ 170.315(f)(1) (Transmission to Immunization Registries).	N/A.
	<i>Measure 2:</i> Syndromic Surveillance Reporting.	§ 170.314(f)(3) (Transmission to Public Health Agencies—Syndromic Surveillance) or § 170.314(f)(7) (Optional—Ambulatory Setting Only—Transmission to Public Health Agencies—Syndromic Surveillance).	§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance) Urgent Care Setting Only.	N/A.
	<i>Measure 3:</i> Electronic Case Reporting	N/A	§ 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting).	N/A.
	<i>Measure 4:</i> Public Health Registry Reporting.	§ 170.314(f)(5) (Optional—Ambulatory Setting Only—Cancer Case Information) and § 170.314(f)(6) (Optional—Ambulatory Setting Only—Transmission to Cancer Registries).	EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries). § 170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys).	EPs may choose to use technologies certified to either the 2014 Edition or 2015 Edition certification criteria in 2017.
	<i>Measure 5:</i> Clinical Data Registry Reporting.	N/A	No 2015 Edition health IT certification criteria at this time.	N/A.

TABLE 14—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 1: Protect Electronic Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.	The requirements are included in the Base EHR Definition.	The requirements are a part of CEHRT specific to each certification criterion.	The requirements are a part of CEHRT specific to each certification criterion.
Objective 2: Electronic Prescribing.	<i>Measure:</i> More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing). § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks).	§ 170.315(b)(3) (Electronic Prescribing).. § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks).	Eligible Hospitals/CAHs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.
Objective 3: Clinical Decision Support.	<i>Measure 1:</i> The eligible hospital or CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.	§ 170.314(a)(8) (Clinical Decision Support).	§ 170.315(a)(9) (Clinical Decision Support).	N/A.
	<i>Measure 2:</i> The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(2) (Drug-Drug, Drug-Allergy Interaction Checks).	§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE).	N/A.
Objective 4: Computerized Provider Order Entry (CPOE).	<i>Measure 1:</i> More than 60% of medication orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(18) (Optional—Computerized Provider Order Entry—Medications).	§ 170.315(a)(1) (Computerized Provider Order Entry—Medications).	N/A.
	<i>Measure 2:</i> More than 60% of laboratory orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(19) (Optional—Computerized Provider Order Entry—Laboratory).	§ 170.315(a)(2) (Computerized Provider Order Entry—Laboratory).	N/A.
	<i>Measure 3:</i> More than 60% of diagnostic imaging orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(20) (Optional—Computerized Provider Order Entry—Diagnostic Imaging).	§ 170.315(a)(3) (Computerized Provider Order Entry—Diagnostic Imaging).	N/A.

TABLE 14—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017—Continued

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 5: Patient Electronic Access.	<p><i>Measure 1:</i> For more than 80% of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information.; and</p> <p>(2) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.</p>	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).</p> <p>§ 170.315(g)(7)* (Application Access—Patient Selection).</p> <p>§ 170.315(g)(8)* (Application Access—Data Category Request)*.</p> <p>§ 170.315(g)(9) (Application Access—All Data Request)*</p> <p>* The three criteria combined are the “API” certification criteria.</p>	<p>Eligible Hospitals/CAHs may use technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., § 170.314(e)(1) or § 170.315(e)(1)) in 2017.</p> <p>The 2014 Edition does not offer “API” certification criteria.</p> <p>Therefore, Eligible Hospitals/CAHs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to § 170.315(g)(7), § 170.315(g)(8), and § 170.315(g)(9).</p>
	<p><i>Measure 2:</i> The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p>	§ 170.314(a)(15) (Patient-Specific Education Resources).	§ 170.315(a)(13) (Patient-Specific Education Resources).	N/A.
Objective 6: Coordination of Care through Patient Engagement.	<p><i>Measure 1:</i> During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the EHR made accessible by the provider and either:</p> <p>(1) view, download or transmit to a third party their health information; or</p> <p>(2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or</p> <p>(3) a combination of (1) and (2).</p>	§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party).	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party).</p> <p>§ 170.315(g)(7) (Application Access—Patient Selection)*.</p> <p>§ 170.315(g)(8) (Application Access—Data Category Request)*.</p> <p>§ 170.315(g)(9) (Application Access—All Data Request)*.</p> <p>* The three criteria combined are the “API” certification criteria.</p>	<p>Eligible Hospitals/CAHs may use technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., § 170.314(e)(1) or § 170.315(e)(1)) in 2017.</p> <p>The 2014 Edition does not offer “API” certification criteria. Therefore, Eligible Hospitals/CAHs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to § 170.315(g)(7), § 170.315(g)(8), and § 170.315(g)(9).</p>
	<p><i>Measure 2:</i> For more than 25% of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	§ 170.314(e)(3) (Secure Messaging).	§ 170.315(e)(2) (Secure Messaging).	N/A.

TABLE 14—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017—Continued

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 7: Health Information Exchange.	<i>Measure 3:</i> Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5% of all unique patients discharged from the eligible hospital or CAH (POS 21 and 23) during the EHR reporting period.	N/A	§ 170.315(e)(3) (Patient Health Information Capture)*.. *Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.	N/A.
	<i>Measure 1:</i> For more than 50% of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record	§ 170.314(b)(2) (Transitions of Care—Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional—Transitions of Care).	§ 170.315(b)(1) (Transitions of Care).	N/A.
	<i>Measure 2:</i> For more than 40% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH receives or retrieves and incorporates into the patient's record in their EHR an electronic summary of care document.	§ 170.314(b)(1) (Transitions of Care—Receive, Display and Incorporate Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional—Transitions of Care).	§ 170.315(b)(1) (Transitions of Care).	N/A.
Objective 8: Public Health and Clinical Data Registry Reporting.	<i>Measure 3:</i> For more than 80% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs clinical information reconciliation.	§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional—Clinical Information Reconciliation and Incorporation).	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).	N/A.
	<i>Measure 1:</i> Immunization Registry Reporting.	N/A	§ 170.315(f)(1) (Transmission to Immunization Registries).	N/A.
	<i>Measure 2:</i> Syndromic Surveillance Reporting.	§ 170.314(f)(3) (Transmission to Public Health Agencies—Syndromic Surveillance).	§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance).	N/A.
	<i>Measure 3:</i> Electronic Case Reporting.	N/A	§ 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting).	N/A.
	<i>Measure 4:</i> Public Health Registry Reporting.	N/A	Eligible Hospitals/CAHs may choose one or more of the following: § 170.315(f)(6) (Transmission to Public Health Agencies—Antimicrobial Use and Resistance).. § 170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys).	EPs may choose to use technologies certified to either the 2014 Edition or 2015 Edition certification criteria in 2017.
<i>Measure 5:</i> Clinical Data Registry Reporting.	No 2015 Edition health IT certification criteria at this time.	N/A.	

TABLE 14—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017—Continued

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<i>Measure 6:</i> Electronic Reportable Laboratory Result Reporting.	§ 170.314(f)(4) (Inpatient Setting Only—Transmission of Reportable Laboratory Tests and Values/Results).	§ 170.315(f)(3) (Transmission to Public Health Agencies—Reportable Laboratory Tests and Values/Results).	N/A.

TABLE 15—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS

Objective	Measure(s)	2015 Edition
Objective 1: Protect Electronic Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.	The requirements are a part of CEHRT specific to each certification criterion.
Objective 2: Electronic Prescribing	<i>Measure:</i> More than 60% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks).
Objective 3: Clinical Decision Support.	<i>Measure 1:</i> The EP must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. <i>Measure 2:</i> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.315(a)(9) (Clinical Decision Support). § 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE).
Objective 4: Computerized Provider Order Entry (CPOE).	<i>Measure 1:</i> More than 60% of medication orders created by the EP during the EHR reporting period are recorded using CPOE. <i>Measure 2:</i> More than 60% of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE. <i>Measure 3:</i> More than 60% of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using CPOE.	§ 170.315(a)(1) (Computerized Provider Order Entry—Medications). § 170.315(a)(2) (Computerized Provider Order Entry—Laboratory). § 170.315(a)(3) (Computerized Provider Order Entry—Diagnostic Imaging).
Objective 5: Patient Electronic Access.	<i>Measure 1:</i> For more than 80% of all unique patients seen by the EP: (1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The EP ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT. <i>Measure 2:</i> The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients seen by the EP.	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party) § 170.315(g)(7) (Application Access—Patient Selection)* § 170.315(g)(8) (Application Access—Data Category Request)* § 170.315(g)(9) (Application Access—All Data Request)* *The three criteria combined are the "API" certification criteria. § 170.315(a)(13) (Patient-specific Education Resources).
Objective 6: Coordination of Care through Patient Engagement.	<i>Measure 1:</i> For 2017, during the EHR reporting period, more than 10% of all unique patients (or patient-authorized representative) seen by the EP actively engage with the EHR made accessible by the provider. An EP may meet the measure by either— (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2). <i>Measure 2:</i> For 2017, more than 25% of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).	§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party) § 170.315(g)(7) (Application Access—Patient Selection)* § 170.315(g)(8) (Application Access—Data Category Request)* § 170.315(g)(9) (Application Access—All Data Request)* *The three criteria combined are the "API" certification criteria. § 170.315(e)(2) (Secure Messaging).

TABLE 15—EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS—Continued

Objective	Measure(s)	2015 Edition
Objective 7: Health Information Exchange.	<i>Measure 3:</i> Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 of all unique patients seen by the EP during the EHR reporting period.	§ 170.315(e)(3) (Patient Health Information Capture)* *Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.
	<i>Measure 1:</i> For more than 50% of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.	§ 170.315(b)(1) (Transitions of Care).
	<i>Measure 2:</i> For more than 40% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP receives or retrieves and incorporates into the patient's record an electronic summary of care document.	§ 170.315(b)(1) (Transitions of Care).
Public Health and Clinical Data Registry Reporting.	<i>Measure 3:</i> For more than 80% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP performs clinical information reconciliation.	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).
	<i>Measure 1:</i> Immunization Registry Reporting	§ 170.315(f)(1) (Transmission to Immunization Registries).
	<i>Measure 2:</i> Syndromic Surveillance Reporting	§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance) Urgent Care Setting Only.
	<i>Measure 3:</i> Electronic Case Reporting	§ 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting).
	<i>Measure 4:</i> Public Health Registry Reporting	EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries) § 170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys).
	<i>Measure 5:</i> Clinical Data Registry Reporting	No 2015 Edition health IT certification criteria at this time.

TABLE 16—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS

Objective	Measure(s)	2015 Edition
Objective 1: Protect Electronic Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.	The requirements are a part of CEHRT specific to each certification criterion.
Objective 2: Electronic Prescribing	<i>Measure:</i> More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.315(b)(3) (Electronic Prescribing). § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks).
Objective 3: Clinical Decision Support.	<i>Measure 1:</i> The eligible hospital or CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.	§ 170.315(a)(9) (Clinical Decision Support).
	<i>Measure 2:</i> The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE).
Objective 4: Computerized Provider Order Entry (CPOE).	<i>Measure 1:</i> More than 60% of medication orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	§ 170.315(a)(1) (Computerized Provider Order Entry—Medications).

TABLE 16—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS—Continued

Objective	Measure(s)	2015 Edition
Objective 5: Patient Electronic Access.	<p><i>Measure 2:</i> More than 60% of laboratory orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.</p> <p><i>Measure 3:</i> More than 60% of diagnostic imaging orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.</p> <p><i>Measure 1:</i> For more than 80% of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information.; and</p> <p>(2) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.</p> <p><i>Measure 2:</i> The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p>	<p>§ 170.315(a)(2) (Computerized Provider Order Entry—Laboratory).</p> <p>§ 170.315(a)(3) (Computerized Provider Order Entry—Diagnostic Imaging).</p> <p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p> <p>§ 170.315(g)(7)* (Application Access—Patient Selection).</p> <p>§ 170.315(g)(8)* (Application Access—Data Category Request)*.</p> <p>§ 170.315(g)(9) (Application Access—All Data Request)*</p> <p>*The three criteria combined are the "API" certification criteria.</p> <p>§ 170.315(a)(13) (Patient-Specific Education Resources).</p>
Objective 6: Coordination of Care through Patient Engagement.	<p><i>Measure 1:</i> During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the EHR made accessible by the provider and either:</p> <p>(1) view, download or transmit to a third party their health information; or</p> <p>(2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or</p> <p>(3) a combination of (1) and (2)</p> <p><i>Measure 2:</i> For more than 25% of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p> <p><i>Measure 3:</i> Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5% of all unique patients discharged from the eligible hospital or CAH (POS 21 and 23) during the EHR reporting period.</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p> <p>§ 170.315(g)(7) (Application Access—Patient Selection)*.</p> <p>§ 170.315(g)(8) (Application Access—Data Category Request)*.</p> <p>§ 170.315(g)(9) (Application Access—All Data Request)*</p> <p>*The three criteria combined are the "API" certification criteria.</p> <p>§ 170.315(e)(2) (Secure Messaging).</p> <p>§ 170.315(e)(3) (Patient Health Information Capture)*.</p> <p>*Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.</p>
Objective 7: Health Information Exchange.	<p><i>Measure 1:</i> For more than 50% of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care— (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.</p> <p><i>Measure 2:</i> For more than 40% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH receives or retrieves and incorporates into the patient's record in their EHR an electronic summary of care document.</p> <p><i>Measure 3:</i> For more than 80% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs clinical information reconciliation.</p>	<p>§ 170.315(b)(1) (Transitions of Care).</p> <p>§ 170.315(b)(1) (Transitions of Care).</p> <p>§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation).</p>
Objective 8: Public Health and Clinical Data Registry Reporting.	<p><i>Measure 1:</i> Immunization Registry Reporting</p> <p><i>Measure 2:</i> Syndromic Surveillance Reporting</p>	<p>§ 170.315(f)(1) (Transmission to Immunization Registries).</p> <p>§ 170.315(f)(2) (Transmission to Public Health Agencies—Syndromic Surveillance).</p>

TABLE 16—ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS—Continued

Objective	Measure(s)	2015 Edition
	<i>Measure 3: Electronic Case Reporting</i>	§ 170.315(f)(5) (Transmission to Public Health Agencies—Electronic Case Reporting).
	<i>Measure 4: Public Health Registry Reporting</i>	Eligible Hospitals/CAHs may choose one or more of the following: § 170.315(f)(6) (Transmission to Public Health Agencies—Antimicrobial Use and Resistance). § 170.315(f)(7) (Transmission to Public Health Agencies—Health Care Surveys).
	<i>Measure 5: Clinical Data Registry Reporting</i>	No 2015 Edition health IT certification criteria at this time.
	<i>Measure 6: Electronic Reportable Laboratory Result Reporting</i>	§ 170.315(f)(3) (Transmission to Public Health Agencies—Reportable Laboratory Tests and Values/Results).

C. Clinical Quality Measurement

1. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2015 and 2016

Under sections 1848(o)(2)(A), 1886(n)(3)(A), and 1814(l)(3)(A) of the Act and 42 CFR 495.4, EPs, eligible hospitals, and CAHs must report on CQMs selected by CMS using certified EHR technology, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs.

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20375 through 20376), we proposed to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs. We summarized the options for CQM submission for providers in the Medicare EHR Incentive Program as follows:

- EP Options for Medicare EHR Incentive Program Participation (*single program participation—EHR Incentive Program only*)

- ++ Option 1: Attest to CQMs through the EHR Registration & Attestation System

- ++ Option 2: Electronically report CQMs through Physician Quality Reporting System (PQRS) Portal

- EP Options for Electronic Reporting for Multiple Programs (*for example: EHR Incentive Program plus PQRS participation*)

- ++ Option 1: Report individual EP’s CQMs through PQRS Portal

- ++ Option 2: Report group’s CQMs through PQRS Portal

We note that under option 2, this may include an EP reporting using the group reporting option, either electronically

using QRDA, or via the GPRO Web Interface.

- Eligible hospital and CAH Options for Medicare EHR Incentive Program Participation (*single program participation—EHR Incentive Program only*)

- ++ Option 1: Attest to CQMs through the EHR Registration & Attestation System

- ++ Option 2: Electronically report CQMs through QualityNet Portal

- Eligible hospital and CAH Options for Electronic Reporting for Multiple Programs (*for example: EHR Incentive Program plus IQR participation*)

- ++ Electronically report through QualityNet Portal

For the Medicaid EHR Incentive Program, we stated that states would continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that states make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for our review and approval prior to being implemented.

We proposed to maintain the existing CQM reporting requirements of nine CQMs covering at least three NQS domains for EPs and 16 CQMs covering at least three NQS domains for eligible hospitals and CAHs (77 FR 54058 for EPs and 77 FR 54056 for eligible hospitals and CAHs).

Beginning in 2015, we proposed to change the definition of “EHR reporting period” in § 495.4 for eligible hospitals and CAHs such that the EHR reporting period would begin and end in relation to a calendar year. In connection with this proposal, we also proposed that in

2015 and for all methods of reporting, eligible hospitals and CAHs would be required to complete a reporting period for clinical quality measures aligned with the calendar year in order to demonstrate meaningful use.

For 2015 only, we proposed to change the EHR reporting period for all EPs, eligible hospitals, and CAHs to any continuous 90-day period within the calendar year. In connection with this proposal, we proposed a 90-day reporting period in 2015 for clinical quality measures for all EPs, eligible hospitals, and CAHs that report clinical quality measures by attestation. We proposed that EPs may select any continuous 90-day period from January 1, 2015 through December 31, 2015, while eligible hospitals and CAHs may select any continuous 90-day period from October 1, 2014 through December 31, 2015, to report CQMs via attestation using the EHR Incentive Program registration and attestation system. We proposed that a provider may choose to attest to a CQM reporting period of greater than 90 days up to and including 1 full calendar year of data.

We further proposed to continue our existing policy that providers in any year of participation for the EHR Incentive Programs for 2015 through 2017 may instead electronically report CQM data using the options previously outlined for electronic reporting either for single program participation in the Medicare EHR Incentive Programs, or for participation in multiple programs if the requirements of the aligned quality program are also met. We noted that EPs seeking to participate in multiple programs with a single electronic submission would be required to submit a full calendar year of CQM data using

the 2014 electronic specifications for the CQMs (which are also known as eCQMs) for a reporting period in 2015. We also noted that eligible hospitals and CAHs seeking to participate in multiple programs with a single electronic submission for a reporting period in 2015 would be required to submit one calendar quarter of data for 2015 from either Q1 (January 1, 2015–March 31, 2015), Q2 (April 1, 2015–June 30, 2015), or Q3 (July 1, 2015–September 30, 2015) and would require of the use of the April 2014 release of the eCQMs. For further information on the requirements for eligible hospitals and CAHs electronically submitting CQMs for a reporting period in 2015 for the Medicare EHR Incentive Program, we referred readers to the FY 2015 IPPS final rule (79 FR 50319 through 50323).

We noted that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the eCQMs.

Comment: We received many comments in support of maintaining the existing CQM reporting requirements and aligning CQM requirements with other quality programs where possible, including support of our proposal to align reporting for eligible hospitals and CAHs to the calendar year. Some commenters expressed concerns over their ability to report CQMs, and some commenters requested that CMS expand the number of CQMs available to specialists.

Response: We appreciate the comments in support of our proposals and understand the concerns raised by others. CMS continues to evaluate the available CQMs for inclusion in the EHR Incentive Programs and will consider adding CQMs to the program as they are developed and found to be appropriate for inclusion. In the meantime, we understand that there are situations in which an EP, eligible hospital or CAH does not have data to report on for a particular CQM, and its EHR is not certified to additional CQMs or does not have additional CQMs available to report on. In these instances, we believe that our policy on allowing zero denominators to be reported allow these providers and specialists to meet the CQM reporting requirements of the EHR Incentive Programs (see the Stage 2 final rule 77 FR 54059 and 54079 and FY 2015 IPPS final rule 79 FR 50323).

Comment: A few commenters suggested that we further align the Medicare EHR Incentive Program with PQRS and allow EPs reporting through a Qualified Clinical Data Registry (QCDR) to satisfy the CQM reporting requirements for meaningful use.

Response: The QCDR reporting mechanism was introduced for the Physician Quality Reporting System (PQRS) beginning in 2014. For 2015, a QCDR is a CMS-approved entity that collects medical and clinical data, or both, for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A QCDR is different from a PQRS qualified registry in that it is not limited to reporting data on measures within the PQRS measure set or the EHR Incentive Program. We appreciate the commenters' suggestion to allow CQM reporting for the EHR Incentive Programs through the PQRS QCDR option and will consider broadening our policy to accept all QCDR submissions in future policy and rulemaking. Currently, EPs can report on CQMs through a QCDR and satisfy some of the requirements for the Medicare EHR Incentive Program, as well as PQRS requirements, if they submit CQMs using certified EHR technology and the approved QRDA-I or QRDA-III format (78 FR 74754 through 74755). We note for the Medicare EHR Incentive Program, the only CQMs that may be reported through a QCDR are those finalized in the Stage 2 final rule (77 FR 54069 through 54075), and this does not include the non-PQRS measures submitted via QCDR.

Comment: Some commenters suggested that reporting on CQMs could be removed as a requirement from the EHR Incentive Program.

Response: As we noted in the Stage 2 final rule (77 FR 54056 through 54078), CQM reporting is a statutory requirement for providers seeking to be meaningful users of certified EHR technology. In addition, as noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20351) and in the Stage 3 proposed rule (80 FR 16740 through 16741), the use of EHR technology to submit information on clinical quality measures is defined in the HITECH Act as a key foundational principle and policy of meaningful use (see sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act). Additionally, we believe CQM reporting is key to the continued efforts to improve the quality of care in a patient centered delivery system reform model. We maintain our commitment to CQM reporting as part of meaningful use of certified EHR technology.

Comment: Many commenters supported our proposal to allow a 90-day reporting period for clinical quality measures for all EPs, eligible hospitals, and CAHs that report clinical quality measures by attestation. Some commenters additionally suggested that

this option should be extended to every year of the EHR Incentive Programs. Some commenters noted that alignment with other quality programs such as PQRS requires full-year reporting even in 2015, and therefore this policy does not align with those quality programs. Commenters also suggested that there be a 90-day reporting period for PQRS.

Response: We appreciate the comments in support of our proposal. We note that our proposal was for 2015 only, and that we are not extending it to 2016 or subsequent years. We also acknowledge that this 90-day reporting period does not fully align with other CMS quality programs such as PQRS, and that each quality program has its own reporting requirements. While we seek to align the CMS quality programs wherever possible and as appropriate, we acknowledge that this is one area where a provider seeking to satisfy the various requirements of multiple programs would need to report data separately to each program, or choose to instead report through one of our aligned options.

After consideration of the public comments, we are finalizing all of the proposals discussed previously as proposed. We note that after these proposals were published, we published the August 17, 2015 FY 2016 IPPS final rule (80 FR 49756 through 49761), which includes additional final policies for eligible hospitals and CAHs reporting CQMs in 2016 for the Medicare EHR Incentive Program.

2. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2017 and Subsequent Years

a. Clinical Quality Measure Reporting Requirements for EPs

In the Stage 3 proposed rule (80 FR 16768), we noted that to further our goals of alignment and avoiding redundant or duplicative reporting across the various CMS quality reporting programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for EPs for 2017 and subsequent years in the Medicare Physician Fee Schedule (PFS) rulemaking, which also establishes the requirements for PQRS and other quality programs affecting EPs. We noted that the form and manner of reporting of CQMs for Medicare EPs would also be included in the PFS, while for Medicaid we would continue to allow the states to determine form and method requirements subject to CMS approval.

We proposed to continue the policy of establishing certain CQM requirements

that apply for both the Medicare and Medicaid EHR Incentive Programs, including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs.

Comment: Commenters supported the alignment efforts between the Medicare EHR Incentive Program and PQRS or other quality programs affecting EPs. Most commenters stated that alignment would reduce burden on EPs and streamline the quality reporting process. Some commenters also appreciated the link between the annual rulemaking cycle and updates to the CQMs stating that aligning CQM requirements for the EHR Incentive Programs with other quality programs in annual rulemaking would require measure developers to revise their CQM specifications more frequently, helping to ensure CQMs reflect the latest clinical evidence.

Response: We appreciate the commenters' support of our proposal, and agree that aligning the Medicare EHR Incentive Program and PQRS or other quality programs affecting EPs would reduce burden on EPs. We also agree that annual rulemaking will allow CMS to ensure that CQMs used in quality reporting programs are updated regularly.

Comment: A few commenters suggested that since CQMs are a requirement of multiple EP quality programs, they could be removed from the EHR Incentive Program requirements because this CQM reporting is redundant.

Response: We appreciate the commenters' suggestion. However, as noted previously, CQM reporting for the EHR Incentive Programs is required by section 1848(o)(2)(A)(iii) of the Act and an integral part of the National Quality Strategy for CMS and HHS as a whole. We further note that in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20375) we stated our intent to maintain these CQM policies as previously finalized. We further believe that by aligning the CQM requirements of the different quality reporting programs, we are reducing burden and removing the redundancy of CQM reporting by allowing EPs to report once for multiple programs.

Comment: Some commenters expressed concerns regarding the amount of time between the publication of the PFS final rule and when the CQMs and policies would go into effect. Many expressed concern over whether their EHR vendor would have time to certify and update their system to the most recent version of the CQMs.

Response: We understand the commenters' concerns and note that CQMs referenced in the PFS rulemaking

are generally updated annually, and certain updates are posted in advance of the final rule. We also note that re-certification of EHR technology is not required for the CQM annual update. Additionally, we have taken steps to align certain aspects of the various CMS quality reporting programs that include the submission of CQMs.

Comment: Other commenters expressed concern about the number of stakeholders involved in these aligned programs, and stated that it would be challenging for EPs to get answers to questions or responses from CMS due to the number of stakeholders involved in CQM submissions.

Response: We understand this concern, and we note that we also continue to align CMS help desks, feedback processes, and other resources to avoid delays in answering questions. We believe that alignment of the CQM requirements along with this coordination effort will greatly reduce burden on EPs.

Comment: While commenters acknowledged the alignment effort to address CQM policies in the PFS rule, some also requested further clarification in regard to how CQM alignment among the programs would work. Specifically, they questioned whether EPs who choose to attest in 2017 would still be required to report to other quality programs, or whether attestation could count for multiple programs.

Response: We appreciate the question and opportunity to further explain this policy, which is a current policy not a new policy. Reporting CQMs by attestation under the EHR Incentive Programs is not an acceptable method of submission for other CMS quality reporting programs because, unlike the EHR Incentive Programs, these other programs have not adopted attestation as a reporting mechanism and also have additional requirements that relate to the results of the CQM calculation. Therefore, reporting CQMs by attestation for the EHR Incentive Programs would not count toward CQM reporting for other quality programs. EPs who choose to report CQMs for the EHR Incentive Programs by attestation in 2017 would need to separately report to other quality programs via one of the approved reporting mechanisms for the particular program.

After consideration of the public comments we received, we intend to continue our policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs, including a common set of CQMs and the reporting periods for CQMs. We intend to address CQM reporting requirements for the

Medicare and Medicaid EHR Incentive Programs for EPs in the PFS rulemaking. We intend to continue to allow the states to determine form and manner of reporting CQMs for their respective state Medicaid EHR Incentive Programs subject to CMS approval.

b. CQM Reporting Requirements for Eligible Hospitals and Critical Access Hospitals

In the Stage 3 proposed rule (80 FR 16769), similar to our intentions for EPs discussed previously, we noted that to further our alignment goal among CMS quality reporting programs for eligible hospitals and CAHs, and avoid redundant or duplicative reporting among hospital programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs for 2016, 2017, and future years, in the Inpatient Prospective Payment System (IPPS) rulemaking. We stated that we intend to include all Medicare EHR Incentive Program requirements related to CQM reporting in the IPPS rulemaking including, but not limited to, new program requirements, reporting requirements, reporting and submission periods, reporting methods, and information regarding the CQMs.

As with EPs, for the Medicaid EHR Incentive Program we would continue to allow the states to determine form and method requirements subject to CMS approval. We proposed to continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs.

Comment: Commenters supported the alignment efforts between the Medicare EHR Incentive Program and Hospital IQR Program. Most commenters stated that alignment would reduce burden on eligible hospitals and CAHs. Some commenters also appreciated the link between the annual rulemaking cycle and updates to the CQMs stating that aligning CQM requirements for the EHR Incentive Program with other quality programs in annual rulemaking would require measure developers to revise their CQM specifications more frequently helping to ensure that CQMs reflect the latest clinical evidence.

Response: We appreciate the commenters' support of our proposal, and agree that aligning the Medicare EHR Incentive Program and the Hospital IQR Program or other quality programs affecting eligible hospitals and CAHs would reduce burdens. We also agree that annual rulemaking will allow CMS

to ensure that CQMs used in quality reporting programs are updated regularly.

Comment: Some commenters expressed concerns regarding the amount of time between the publication of the IPPS final rule and when the CQMs and policies would go into effect. Many expressed concern over whether their EHR vendor would have time to certify and update their system to the most recent version of the CQMs, and a few went on to request that changes to CQMs and submission requirements not change from one quarter reporting period to the next.

Response: We understand the commenters' concerns and note that CQMs referenced in the IPPS rulemaking are generally updated annually, and certain updates are posted in advance of the final rule. The 2016 IPPS final rule provides flexibility to eligible hospitals and CAHs needing to update their EHR systems only for the most recent version of the CQMs. No changes to 2014 CEHRT criteria or timelines are being finalized in this final rule with comment period.

Comment: Some commenters expressed concerns related to CMS' ability to accept electronically submitted CQMs.

Response: We understand the commenters' concerns. CMS has worked to continually develop and improve its CQM receiving system for the purposes of collecting CQMs electronically.

Comment: Some commenters noted that the Hospital IQR Program is not required for CAHs and requested clarification on how the alignment of the Medicare EHR Incentive Program and Hospital IQR Program would impact CAHs seeking to electronically submit their CQM data.

Response: We agree that the Hospital IQR Program is not required for CAHs. Only subsection (d) hospitals are subject to the requirements and payment reductions of the Hospital IQR Program. For the EHR Incentive Programs, CAHs may continue to report their CQM data by attestation in CY 2016. However, we encourage CAHs to submit their CQMs electronically through the QualityNet portal. We believe electronic submission of CQMs is an important next step in the meaningful use of certified EHR technology, and encourage CAHs to begin submitting CQMs electronically in 2016. We further note that in section II.C.4 of this final rule with comment period, we finalize our policy to require the electronic submission of CQMs starting in 2018 and thus encourage CAHs to begin electronically reporting CQMs as soon as feasible.

After consideration of the public comments we received, we intend to continue our policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs, including a common set of CQMs and the reporting periods for CQMs. We intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs in the IPPS rulemaking. We intend to continue to allow the states to determine form and manner of reporting CQMs for their respective state Medicaid EHR Incentive Programs subject to CMS approval.

c. Quality Reporting Data Architecture Category III (QRDA-III) Option for Eligible Hospitals and CAHs

In the Stage 3 proposed rule (80 FR 16771), we proposed to remove the QRDA-III option for eligible hospitals and CAHs, as we believe the CQM calculations, per the QRDA-III, are not advantageous to quality improvement in a hospital setting. We noted that as the EHR Incentive Programs further aligns with the Hospital IQR Program, we intend to continue utilizing the electronic reporting standard of QRDA-I patient level data that we finalized in the FY 2015 IPPS rule (79 FR 50322), which will allow the same level of CQM reporting, and use and analysis of these data for quality improvement initiatives.

We also proposed that states would continue to have the option, subject to our prior approval, to allow or require QRDA-III for CQM reporting.

We received comments regarding these proposals in response to the Stage 3 proposed rule, as well as comments regarding the QRDA-III option in response to the FY 2016 IPPS/LTCH PPS proposed rule. We considered these comments and responded to them in the FY 2016 IPPS/LTCH PPS final rule, and we finalized our proposal to remove the QRDA-III as an option for reporting under the Medicare EHR Incentive Program. We stated that for 2016 and future years, we are requiring QRDA-I for CQM electronic submissions for the Medicare EHR Incentive Program. We also noted that states would continue to have the option, subject to our prior approval, to allow or require QRDA-III for CQM reporting. For more information, we refer readers to the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760).

3. CQM Reporting Period Beginning in 2017

In the Stage 3 proposed rule (80 FR 16773), we proposed to require an EHR

reporting period of one full calendar year for meaningful use for providers participating in the Medicare EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time (80 FR 16779). We proposed to require the same length for the CQM reporting period for EPs, eligible hospitals, and CAHs beginning in 2017. We proposed a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR reporting period.

a. CQM Reporting Period for EPs

We proposed to require a CQM reporting period of one full calendar year for all EPs participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR reporting period. We proposed these reporting periods would apply beginning in CY 2017 for all EPs participating in the EHR Incentive Program.

Comment: Most commenters supported one full calendar year of reporting for EPs participating in the EHR Incentive Programs. Some commenters stated that they believed this would result in more complete and accurate data. A few commenters stated that no exception should be granted for Medicaid providers demonstrating meaningful use for the first time because this exception would cause confusion. A commenter recommended that under this exception, we allow the 90-day reporting period for CQMs to be different than the 90-day EHR reporting period.

Response: We appreciate the comments in support of our proposal, and we agree that a full year of reporting would lead to more complete data. However, we believe that a 90-day CQM reporting period is appropriate for the Medicaid EHR Incentive Program when the EP is attesting to meaningful use for the first time. A 90-day CQM reporting period would allow Medicaid EPs additional time and flexibility within their first year of demonstrating meaningful use to implement certified EHR technology and otherwise integrate the meaningful use objectives into their practices. We also believe that it would reduce the burden on states to implement significant policy and system changes in preparation for Stage 3, as the 90-day period for the first year

of meaningful use is consistent with our previous policies and meaningful use timelines. We agree with the commenter's recommendation that we not require the reporting period for CQMs to be the same 90-day period as the EHR reporting period under the exception proposed for Medicaid. We believe it is appropriate for the CQM reporting period to be any continuous 90-day period in the calendar year for providers demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. This will give providers flexibility with attesting and would not require states to make system changes as there are 90-day reporting periods under the current policy.

Comment: Some commenters opposed the proposal stating that there is additional work that needs to be done to assess the feasibility, accuracy, and reliability of electronically reported data, while others stated that requiring one calendar year of electronically submitted data creates additional burden on EPs to collect that data. A few commenters suggested a 90-day reporting period for all EPs in 2018 when electronic reporting is required.

Response: We understand the commenters' concerns and note that CMS continues to assess electronically reported data for accuracy and reliability. If data is determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance. Additionally we note that one calendar year of data is required for PQRS and other quality reporting programs with which we seek to align the EHR Incentive Program; this alignment reduces provider burden by allowing EPs to report once for multiple programs. We believe full year reporting is necessary for the efficacy of quality measurement and quality improvement planning, and, in fact, most CQMs are designed to be collected over a 12-month period, including multiple variables to track change over time. As mentioned in the Stage 3 proposed rule, we believe full year CQM reporting will allow for the collection of more comparable data across CMS quality programs, increase alignment across those programs, and reduce the complexity of reporting requirements for the Medicare EHR Incentive Program by streamlining the reporting timeline for providers for CQMs and meaningful use objectives and measures (79 FR 16769). While we are allowing a 90-day EHR reporting period for EPs who demonstrate Stage 3 in 2017, we do not believe it is necessary to similarly allow returning participants who are participating in Stage 3 to also use a 90-

day reporting period for CQMs for 2017. The shorter reporting period for Stage 3 participants is intended to ease the transition to the new Stage 3 objectives and measures and higher thresholds. There is no such difference between the CQM requirements for Stage 3 participation in 2017 versus participation meeting the objectives and measures outline for use in 2015 through 2017 in section II.B.2.a of this final rule with comment period.

Note that there is also a 90-day EHR reporting period permitted in 2017 for EPs participating for the first time in either the Medicare or Medicaid EHR Incentive Programs. Consistent with prior program years, we are permitting EPs participating for the first time in 2017 to use a 90-day reporting period for CQMs.

After considering the public comments we received, we are finalizing our proposal to require a CQM reporting period of one full calendar year for EPs participating in the Medicare and Medicaid EHR Incentive Programs starting in 2017. We are finalizing with modification our proposal of a limited exception for EPs demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. For these EPs, the reporting period for CQMs would be any continuous 90-day period within the CY, with the modification that it could be a different 90-day period than their EHR reporting period for the incentive payment under Medicaid.

b. CQM Reporting Period for Eligible Hospitals and CAHs

For eligible hospitals and CAHs in 2017 and subsequent years, in the Stage 3 proposed rule (80 FR 16770) we proposed to require a reporting period of one full calendar year which consists of 4 quarterly data reporting periods for providers participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR reporting period. We stated that more details of the form and manner will be provided in the IPPS rulemaking cycle.

Comment: Most commenters supported one full calendar year of reporting for eligible hospitals and CAHs participating in the EHR Incentive Programs. Some commenters stated that they believed this would result in more complete and accurate data, and others expressed support for a consistent reporting period across reporting programs. Some commenters opposed

the proposal stating that there is additional work that needs to be done to assess the feasibility, accuracy, and reliability of electronically submitted data. Some commenters opposed the proposal stating that it creates additional burden on eligible hospitals and CAHs to collect the data, and some went on to suggest that CMS continue the validation pilot instead of requiring one full year of electronically submitted data in 2018. A few commenters suggested a 90-day reporting period for all eligible hospitals and CAHs in 2018 when electronic reporting is required. A commenter recommended that under the limited exemption for Medicaid eligible hospitals and CAHs, we should allow the 90-day reporting period for CQMs to be different than the 90-day EHR reporting period.

Response: We appreciate the comments we received in support of our proposal, and agree that accepting one full year of data will result in more complete and accurate data. We understand the concerns stated by commenters regarding the additional burden and efforts associated with collecting this data, but we note that providers would be able to submit one full year of data for both the EHR Incentive Program and the Hospital IQR Program, thereby reducing provider burden. We further note that CMS continues to assess electronically submitted data for accuracy and reliability. If data is determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance.

While we are allowing a 90-day EHR reporting period for eligible hospitals and CAHs who demonstrate Stage 3 in 2017, we do not believe it is necessary to similarly allow returning participants who are participating in Stage 3 to also use a 90-day reporting period for CQMs for 2017. The shorter reporting period for Stage 3 participants is intended to ease the transition to the new Stage 3 objectives and measures and higher thresholds. There is no such difference between the CQM requirements for Stage 3 participation in 2017 versus participation meeting the objectives and measures outlined for use in 2015 through 2017 in section II.B.2.a. of this final rule with comment period.

Note that there is also a 90-day EHR reporting period permitted in 2017 for eligible hospitals and CAHs participating for the first time in either the Medicare or Medicaid EHR Incentive Programs. Consistent with prior program years, we are permitting eligible hospitals and CAHs

participating for the first time in 2017 to use a 90-day reporting period for CQMs.

After consideration of the public comments that we received, we are finalizing our proposal to require a reporting period of one full calendar year which consists of 4 quarterly data reporting periods starting in 2017 for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Program. We are finalizing with modification our proposal of a limited exception for eligible hospitals and CAHs demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. For these eligible hospitals and CAHs, the reporting period for CQMs would be any continuous 90-day period within the CY, with the modification that it could be a different 90-day period than their EHR reporting period for the incentive payment under Medicaid. More details of the form and manner will be provided in the IPPS rulemaking cycle.

c. Reporting Flexibility for EPs, Eligible Hospitals, and CAHs in 2017

We proposed that EPs, eligible hospitals, and CAHs would be able to have more flexibility to report CQMs in one of two ways in 2017—via electronic reporting or attestation (80 FR 16770). First EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016. Alternately, a provider may choose to continue to

attest also using the most recent (2016 version) eCQM electronic specifications.

Comment: Commenters supported our proposal to allow more flexibility in 2017 reporting. Most commenters supported a move toward electronic reporting, and also agreed that attestation should remain an option for 2017 to provide options to, and reduce burden on EPs, eligible hospitals, and CAHs. Some commenters supported our proposal but urged CMS to make electronic reporting mandatory in 2018 or move up the timeline to require mandatory electronic reporting as soon as possible.

Response: We appreciate the comments in support of our proposal, and agree with commenters' statements that flexibility reduces burden on EPs, eligible hospitals, and CAHs. We also appreciate commenters' support of a move toward electronic reporting, and requiring electronic reporting in 2018 or moving up the timeline for mandatory electronic reporting. We believe electronic reporting is an important step in demonstrating meaningful use of certified EHR technology and note that in section II.C.4 of this final rule with comment period, we are finalizing our proposal to require electronic reporting in 2018 where feasible.

After consideration of these public comments, we are finalizing this policy as proposed.

4. Reporting Methods for CQMs

In the Stage 3 proposed rule (80 FR 16770), starting in 2017, we proposed to continue to encourage electronic submission of CQM data for all EPs, eligible hospitals, and CAHs where feasible. However, as outlined in section

II.C.1.b. of the Stage 3 proposed rule (80 FR 16770), we would allow attestation for CQMs in 2017.

For 2018 and subsequent years, we proposed that providers participating in the Medicare EHR Incentive program must electronically report where feasible and that attestation to CQMs would no longer be an option except in certain circumstances where electronic reporting is not feasible. This would include providers facing circumstances which render them unable to electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible for their demonstration of meaningful use for a given year. We noted that we intend to address the form and manner of electronic reporting in future Medicare payment rules.

For the Medicaid EHR Incentive Program, as in the Stage 2 rulemaking (77 FR 54089), we proposed that states would continue in Stage 3 to be responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to continue to allow reporting through attestation. If a state does require such electronic reporting, the state is responsible for sharing the details of the process with its provider community. We proposed for Stage 3 that the states would establish the method and requirements, subject to our prior approval, for the electronic capture and reporting of CQMs from CEHRT. We have included Table 17 in this final rule with comment period as a summary of our proposals (80 FR 16770).

TABLE 17—PROPOSED ECQM REPORTING TIMELINES FOR MEDICARE AND MEDICAID EHR INCENTIVE PROGRAM

Year	2017 Only	2017 Only	2018 and Subsequent years	2018 and Subsequent years
Reporting method available Provider Type who May Use Method.	Attestation All Medicare providers Medicaid providers must refer to state require- ments for reporting.	Electronic Reporting All Medicare Providers Medicaid providers must refer to state require- ments for reporting.	Attestation Medicare Providers with circumstances rendering them unable to eReport. Medicaid providers must refer to state require- ments for reporting.	Electronic Reporting All Medicare Providers Medicaid providers must refer to state require- ments for reporting.
CQM Reporting Period	1 CY for Medicare 1 CY for returning Med- icaid. 90 days for first time meaningful user Med- icaid.	1 CY for Medicare 1 CY for returning Med- icaid. 90 days for first time meaningful user Med- icaid.	1 CY for Medicare 1 CY for returning Med- icaid. 90 days for first time meaningful user Med- icaid.	1 CY for Medicare 1 CY for returning Med- icaid 90 days for first time meaningful user Med- icaid.
eCQM Version Required ... (CQM electronic specifica- tions update).	2016 Annual Update	2016 Annual Update	2016 Annual Update or more recent version.	2017 Annual Update.
CEHRT Edition Required ..	2014 Edition Or 2015 Edi- tion.	2014 Edition Or 2015 Edi- tion.	2015 Edition	2015 Edition

Comment: Most commenters supported the move to electronic reporting; however, they did so with caution. Commenters expressed their support, as well as concerns, related to the feasibility of the move to electronic reporting of CQMs citing issues with data submission and the reliability of CQMs. Some commenters expressed concerns about committing to a timeline for implementing electronic reporting of CQMs stating that they had concerns about future updates to CQMs and the difficulties eligible hospitals face in implementing CQMs currently.

Response: We appreciate the comments in support of our move to electronic reporting, and understand some of the concerns that come along with that move. CMS continues to evaluate the accuracy and reliability of CQM data received from providers. We believe that it is important to set a timeline for requiring electronic reporting and to give EPs, eligible hospitals, CAHs and their EHR vendors time to prepare for this requirement.

Comment: A few commenters requested clarification as to which CQM version would be accepted via attestation.

Response: We appreciate the comments and the opportunity to clarify our policy. For 2017 reporting, we will accept the 2016 version of the CQM specifications for both attested and electronically reported CQMs. For 2018 reporting, we will accept the 2017 version of the CQM specifications for both attested and electronically reported CQMs. For 2018, we will additionally accept the 2016 version of the CQM specifications for attestation. We note that attestation in 2018 will be allowed for providers facing circumstances which render them unable to electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible, and we are therefore allowing either the 2016 or 2017 version of the CQM specifications due to this exception.

Comment: A few commenters stated that since attestation to core objectives is a manual process, CQM submission should also remain a manual process and the two should not be split.

Response: We believe that electronic reporting is a valuable step in demonstrating meaningful use and helps us to reach our goal of alignment with other quality reporting programs. In addition, we note that the data received via electronic reporting is valuable and necessary for quality improvement.

Comment: A few commenters suggested that CMS should direct states on reporting method to prevent too much variation among the state and federal programs.

Response: While we appreciate the commenters' suggestion, we believe that, consistent with our policy in previous years for the EHR Incentive Programs, the reporting method for CQMs in the Medicaid EHR Incentive Program is an operational question that is best left to state discretion subject to our approval. Allowing states flexibility with respect to the reporting method for CQMs permits states to continue using attestation or to pursue other options such as electronic reporting. We believe this is appropriate given the varying capabilities and policies among states regarding CQM submission.

We are finalizing our policy as proposed, that in 2017 all providers have two options to report CQM data, either through attestation or through use of established methods for electronic reporting where feasible. Starting in 2018, providers participating in the Medicare EHR Incentive Program must electronically report where feasible and that attestation to CQMs would no longer be an option except in certain circumstances where electronic reporting is not feasible. We are also finalizing our proposal that for the Medicaid EHR Incentive Program states would continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to continue to allow reporting through attestation. We note that if a state does require such electronic reporting, the state is responsible for sharing the details of the process with its provider community. We also note that the states would establish the method and requirements, subject to our prior approval, for the electronic capture and reporting of CQMs from CEHRT.

5. CQM Specification and Changes to the Annual Update

In the Stage 3 proposed rule (80 FR 16771), we recognized that it may be necessary to update CQM specifications after they have been published to ensure their continued clinical relevance, accuracy, and validity. CQM specification updates may include administrative changes, such as adding the NQF endorsement number to a CQM, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a CQM. These changes are described through the annual updates to the electronic specifications for EHR submission published by CMS. Because

we require the most recent version of the CQM specifications to be used for electronic reporting methods, we understand that EHR vendors must make CQM updates on an annual basis and providers must regularly implement those updates to stay current with the most recent CQM version.

In the Stage 3 proposed rule (80 FR 16771), we proposed no changes to our policy on updating CQM specifications. However, we stated that we will continue to evaluate the CQM update timeline and look for ways to provide CQM updates timely, so that vendors can develop, test, and deploy these updates and providers can implement those updates as necessary.

We received many comments in response to our request for comments. However, we note that we did not make any specific proposal in regard to the annual update process for CQMs.

Comment: Many commenters expressed concerns regarding the timing and frequency of annual updates. Several stated that EHR vendors need more time to update the CQMs in their EHRs and suggested updates should be minimal, or that the new specifications for CQMs should be released well in advance of their implementation. A few commenters suggested that the CQM updates should be more frequent, such as monthly, to address changes in clinical guidance and to keep the CQMs relevant.

Response: We appreciate both perspectives on this subject and note that the CQM specifications are posted at least 6 months prior to the reporting period. We believe it is important to reflect the most recent clinical guidance in CQMs, and therefore seek to find an appropriate balance between the timing of the posting of CQM specifications and the reporting period for those CQMs.

Comment: Some commenters suggested that recertification should be required with each update to the CQMs.

Response: At this time, we do not require recertification with the annual update, but instead strongly recommend and encourage EHR vendors to test their products against CMS verification tools and receiving systems.

Comment: Some commenters suggested that CMS have some flexibility in when a CQM can be updated in order to address those situations where a CQM required an update mid-year. For example, these commenters suggested that CMS be able to update or suspend the use of that CQM at any point during the year.

Response: We appreciate all comments received in regard to the annual update process, and will take

them into consideration for future rulemaking and policy development. We note that we did not make any specific proposals in the Stage 3 proposed rule, and thus are not finalizing any change to our policy at this time.

6. Certified EHR Technology Requirements for CQMs

In the 2014 Edition EHR Certification Criteria Final Rule, ONC finalized certain certification criteria to support the meaningful use objectives and CQMs set forth by CMS. In that rule, ONC also specified that in order for an EP, eligible hospital, or CAH to have EHR technology that meets the Base EHR definition, the EHR technology must be certified to a minimum of nine CQMs for EPs or 16 CQMs for eligible hospitals and CAHs (77 FR 54264 through 54265; see also 45 CFR 170.102). This is the same number required for quality reporting to the Medicare and Medicaid EHR Incentive Programs, the PQRS EHR reporting and, beginning in 2015, the electronic reporting option under the Hospital IQR Program.

As stated in the Stage 3 proposed rule (80 FR 16771 through 16772), we believe EHRs should be certified to more than the minimum number of CQMs required by one or more CMS quality reporting programs so that EPs, eligible hospitals, and CAHs have a choice of which CQMs to report, and could therefore choose to report on CQMs most applicable to their patient population or scope of practice.

We realize that requiring EHRs to be certified to more than the minimum number of CQMs required by the Medicare and Medicaid EHR Incentive Programs may increase the burden on EHR vendors. However, in the interest of EPs, eligible hospitals, and CAHs being able to choose to report eCQMs that represent their patient populations, we would like to see EP vendors certify to all eCQMs that are in the EP selection list, or eligible hospital/CAH vendors certify to all eCQMs in the selection list for those stakeholders.

We are also considering a phased approach such that the number of CQMs required for the vendors to have certified would increase each year until EHR products are required to certify all CQMs required for reporting by EPs, eligible hospitals, and CAHs. For example, in year one of this phased plan, we might require that EHRs be certified to at least 18 of 64 available CQMs for EPs and 22 of 29 available CQMs for eligible hospitals and CAHs; in year two, we might require at least 36 CQMs for EPs and all 29 CQMs for

eligible hospitals and CAHs; in subsequent years of the plan, we would increase the number of required CQMs for EPs until the EHR is certified to all applicable CQMs for EPs, eligible hospitals, and CAHs.

We have also considered alternate plans that would require EHRs to be certified to more than the minimum number of CQMs required for reporting, but would not require the EHR to be certified to all available CQMs. For example, we might require that EHRs be certified to a certain core set of CQMs plus an additional 9 CQMs for EPs, and a certain core set of CQMs plus an additional 16 CQMs for eligible hospitals and CAHs, which the EHR vendor could choose from the list of available CQMs.

We note that the specifics of this plan would be outlined in separate notice-and-comment rulemaking such as the PFS or IPPS rules. In the Stage 3 proposed rule (80 FR 16771 through 16772), we sought comment on a plan to increase the number of CQMs to which an EHR is certified.

Comment: We received many comments in support of a plan to require EHR vendors to certify to more than the minimum required CQMs, and several comments in support of a plan to have EHR vendors certify to all CQMs. Most commenters stated that either approach would reduce burden on EPs, eligible hospitals, and CAHs by allowing them to choose which measures to report instead of being forced to report on only those CQMs to which their EHR is certified. Commenters also stated that having more CQMs to choose from would reduce the number of zero denominators that are reported to CMS because EPs, eligible hospitals, and CAHs would have better access to CQMs for which they have patient data. Some commenters also proposed alternative plans such as a requirement to have EHRs certify to “capture and export” all CQMs, but not necessarily to “calculate and report” those CQMs, or to have all consumers of CQM data, including states, private payers, etc., agree on one set of CQMs to be reported.

A few commenters opposed any plan to require a certain number of CQMs to which EHRs must be certified stating that EHR vendors should be allowed to choose CQMs based on their provider population or specialty product. Some commenters opposed the plan to certify to all CQMs because of the burden it would place on EHR vendors, and because it would force EHRs to be certified to CQMs that are not relevant to the EHR’s provider population. Other commenters expressed concern about a

plan to certify to all CQMs, even in a phased approach, because they were unclear about the number and quality of the CQMs to be included in future years of the EHR Incentive Program. Lastly, some commenters expressed concern about the burden this plan could place on EPs, eligible hospitals, and CAHs because of the added effort it would take to implement these measures in their provider setting.

Response: We appreciate all of the comments we received in regard to the plans we outline in the proposed rule(s). We note that we did not make any proposals to implement these plans, and we will not be finalizing any policy regarding a requirement to have EHRs certify to a certain number of CQMs. We agree with the majority of commenters that EHRs should be required to certify to more than the minimum number of CQMs for reporting. However, we are still determining what that number should be, and will take these comments into consideration as we continue to develop that policy.

7. Electronic Reporting of CQMs

As previously stated in the Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (77 FR 54051 through 54053) and restated in the Stage 3 proposed rule (80 FR 16772), CQM data submitted by EPs, eligible hospitals, and CAHs are required to be captured, calculated, and reported using certified EHR technology. We do not consider the manual abstraction of data from a patient’s chart to be capturing the data using certified EHR technology. We believe that electronic information interfaced or electronically transmitted from non-certified EHR technology, such as lab information systems, automated blood pressure cuffs, and electronic scales, into the certified EHR, would satisfy the “capture” requirement, as long as that data is visible to providers in the EHR.

Comment: We received several comments regarding the manual extraction of data from a patient’s chart. Specifically, a few commenters objected to the loss of opportunity to manually extract data from a patient’s chart, and a few stated their need to continue extracting data from a patient’s chart.

Response: We did not make any proposals on this subject in the Stage 3 proposed rule, but noted that we do not consider the manual abstraction of data from the EHR to be capturing the data using certified EHR technology (80 FR 16772). Explanation of our goal to transition from manual abstraction of data to electronic reporting for hospital reporting can be found in the Medicare and Medicaid EHR Incentive Programs

Stage 2 final rule (77 FR 54078 through 54079).

D. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

In the EHR Incentive Programs for 2015 through 2017 and the Stage 3 proposed rules, we proposed to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs (80 FR 20376 and 80 FR 16772). The demonstration methods we adopt for Medicare will automatically be available to the states for use in their Medicaid programs.

b. Methods for Demonstration of the Criteria for Meaningful Use in 2015 through 2017

As mentioned previously in section II.B.1.b.(2). of this final rule with comment period, we are redesignating the numbering of certain sections of the regulation text under part 495. In prior rules, we defined the criteria for the demonstration of meaningful use at § 495.8, which is redesignated as § 495.40. We defined the criteria for the demonstration of meaningful use at § 495.40, including references to the objectives and measures as well as the requirement to report CQMs. In order to demonstrate meaningful use in 2015 through 2017, we proposed (80 FR 20374) that the requirements at § 495.40 include a reference to the objectives and measures for 2015 through 2017 outlined at § 495.22 which the provider must satisfy (80 FR 20376).

We proposed to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the objectives and measures of meaningful use. Instead of individual Medicare EP attestation through the CMS Registration and Attestation System, we also proposed to continue the existing optional batch file process for attestation. Further, we proposed changes to the deadlines for EPs, eligible hospitals, and CAHs to demonstrate meaningful use in 2015 and 2016; as well as specific changes to the deadlines for providers to demonstrate meaningful use for the first time in 2015 and 2016 in order to avoid a payment adjustment in the subsequent year.

Comment: A number of commenters requested additional support for providers seeking to attest for an EHR reporting period in 2015 given the proposed changes for the program in 2015.

Response: We understand the need to provide information for providers as quickly as possible and will work to create educational guides, FAQs, tip sheets, and other tools to support providers seeking to meet the requirements of the EHR Incentive Program for an EHR reporting period in 2015.

After consideration of the comments received, we are finalizing our proposal to maintain attestation as the demonstration method for EHR reporting periods in 2015 through 2017 and the corresponding regulation text at § 495.40.

c. Attestation Deadlines for the EHR Incentive Programs in 2015 through 2017

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20376), we proposed changes to the attestation deadlines for eligible hospitals and CAHs in connection with the proposal that these providers must complete an EHR reporting period between October 1, 2014 and the end of the calendar year (CY) on December 31, 2015, and complete an EHR reporting period for 2016 between January 1, 2016 and December 31, 2016. Specifically, we proposed changes to the attestation deadlines as follows:

- For an EHR reporting period in 2015, an eligible hospital or CAH must attest by February 29, 2016.
- For an EHR reporting period in 2016, an eligible hospital or CAH must attest by February 28, 2017.

In addition, we noted that providers would not be able to attest for an EHR reporting period in 2015 prior to January 1, 2016 in order to allow adequate time to make the system changes necessary to accept attestations. This change would not delay incentive payments for Medicare EPs because 2015 cannot be an EP's first payment year under section 1848(o)(1)(B)(v) of the Act. Thus, all EPs who qualify for an incentive payment for 2015 would be returning participants in the program and would have had the full CY 2015 as their EHR reporting period under our current policy. We received the following comments and our response follows:

Comment: A number of commenters requested that CMS allow providers to attest to an EHR reporting period for 2015 prior to the finalization of the proposals contained in the EHR Incentive Programs in 2015 through 2017 proposed rule for various reasons, including concerns about the load on CMS systems in the attestation period if all providers attest at the same time. Others commenters expressed similar

concerns if hospital attestations are added to that total. Finally, a number of commenters requested that systems be opened early to allow eligible hospitals that are attesting for the first time to earn an incentive payment as quickly as possible.

Response: First, we note that under the Administrative Procedure Act, we could not accept attestations for 2015 that are based solely on proposals made in a notice of proposed rulemaking. Second, as we stated in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20376), the majority of eligible professionals would have been attesting for an EHR reporting period in 2015 of one full year at the close of CY 2015. This means that the high volume of attestations in January and February of 2015 has already been anticipated and preparations for that time have been made. Therefore, we do not expect the proposed changes to the attestation deadlines would significantly increase the load on CMS systems, and even with full participation among eligible hospitals and CAHs, only an additional 4,000 attestations would be received at the close of the calendar year with the shift from fiscal year to calendar year reporting for these providers.

Comment: A number of commenters requested an extension of the attestation period following the close of the year for EHR reporting periods in 2015. Some of these commenters recommended that data submission be allowed for 3 months or for 6 months following the close of the calendar year. Other commenters stated that large organizations need more time to complete attestations. A number of commenters requested that CMS allow greater flexibility in prolonging an attestation period for 2015 only. Still other commenters noted that there may be a lag after the end of the reporting period before all data can be collected and validated. These commenters suggested that we allow for a longer period of time in which to attest after the reporting period, which would allow for accurate collection, validation, documentation, and attesting to the data. Other commenters noted the volume of attestations and requested additional time, as the volume of providers that will be completing their attestations during that time period may tax the system and cause extensive delays while entering the data.

Response: We believe that an attestation period of 2 months following the close of the calendar year (February 29, 2016 for an EHR reporting period in 2015) is appropriate because it is consistent with our current policy of

requiring attestation within the 2 months after the close of the fiscal year for returning eligible hospitals and CAHs or calendar year for returning EPs. We further note that this attestation period also aligns with the submission period for CQM reporting for PQRS. We understand the concern over a high volume of attestations. However, as noted previously, we do not anticipate that the proposed changes to the attestation deadlines would significantly increase the volume over what was expected for 2015. In addition, as we have done in past years, we will monitor progress, attestation volume, and provider readiness in real time as the attestation period progresses.

Comment: A commenter requested that we clarify how the requirements of the program prior to the final rule relate to those after the effective date of the final rule in terms of the attestation windows and selection of an EHR reporting period. The commenter requested that new participants be able to attest to the current Stage 1 objectives and measures even after the effective date of this final rule with comment period for an EHR reporting period in 2015. The commenter also requested guidance on whether states will be required to take an approach consistent with CMS on this issue.

Response: Any attestations accepted by a state for the Medicaid EHR Incentive Program prior to the effective date of this final rule with comment period must meet the requirements in effect at that time for the Medicaid EHR Incentive Program. In addition, the objectives and measures of meaningful use apply to both the Medicare and Medicaid EHR Incentive Programs, and the demonstration methods we adopt for Medicare would automatically be available to the states for use in their Medicaid programs.

We refer the commenter to sections II.B.1.b.(4).(a). and II.E. of this final rule with comment period for an explanation of when in 2015 the 90-day EHR reporting period and EHR reporting period for a payment adjustment year may occur. We further note that CMS will not be accepting attestations for an EHR reporting period in 2015 and subsequent years for any objective or measure which has been removed in this final rule with comment period in section II.B.1.b.(4).(b).

Comment: A commenter stated that providers believe that the management of attestation deadlines and payment adjustments is very complicated and difficult to follow.

Response: We note that this is part of the motive behind some of the changes to reporting periods for the Medicare

and Medicaid EHR Incentive Programs. We further note that while this final rule with comment period makes additional changes to the program, we believe these changes will help to settle the program into a more regular and predictable schedule for all participants.

After consideration of the comments received, we are finalizing the attestation deadlines for meaningful use in 2015 and 2016 as proposed. We note that any EP, eligible hospital or CAH that attested to meaningful use for the first time under Medicare or Medicaid for an EHR reporting period in 2015 prior to the effective date of this final rule with comment period will not be required to submit a new attestation.

d. New Participant Attestation Deadlines for Meaningful Use in 2015 and 2016 To Avoid a Payment Adjustment

In § 495.4, the definition of an EHR reporting period for a payment adjustment year establishes special deadlines for attestation for EPs and eligible hospitals that are demonstrating meaningful use for the first time in the year immediately preceding a payment adjustment year. In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20376), we noted that we are proposing a later deadline for attestation for 2015 only to allow enough time for all providers to complete a 90-day EHR reporting period after the anticipated effective date of the final rule. We proposed changes to the attestation deadlines for purposes of the payment adjustment years for EPs, eligible hospitals, and CAHs in the EHR Incentive Programs in 2015 through 2017 proposed rule at 80 FR 20380 and 20381. We address those proposals and respond to the comments received in section II.E.2. of this final rule with comment period.

e. Methods for Demonstration of the Stage 3 Criteria of Meaningful Use for 2017 and Subsequent Years

We proposed to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the Stage 3 objectives and measures. We proposed to continue the existing optional batch file process for attestation in lieu of individual Medicare EP attestation through our registration and attestation system. This batch reporting process ensures that the objectives and measures of the program and the use of certified EHR technology continues to be measured at the individual level, while promoting efficiencies for group practices that must submit attestations

on large groups of individuals (77 FR 54089).

We stated that we would continue to leave open the possibility for CMS and the states to test options for demonstrating meaningful use that utilize existing and emerging HIT products and infrastructure capabilities. These options could involve the use of registries or the direct electronic reporting of measures associated with the objectives. We would not require any EP, eligible hospital, or CAH to participate in this testing in order to receive an incentive payment or avoid the payment adjustment.

For 2017 only, we proposed changes to the attestation process for the meaningful use objectives and measures, which would allow flexibility for providers during this transitional year (80 FR 16772).

Comment: A few commenters suggested that EHR Incentive Program attestation be automated. EPs, eligible hospitals, or CAHs should be able to use their certified EHR technology to directly share EHR Incentive Program performance data with CMS, eliminating the need for the manual input of data into the agency's attestation portal. Allowing automated EHR Incentive Program attestation will improve participation in the program, cut down on possible manual input errors, and be more in line with the intent of supporting interoperability and the seamless transfer of electronic health care performance data.

Response: We note that in the Stage 2 proposed rule we requested input on the potential of developing an automated electronic reporting system for the objectives and measures of the EHR Incentive Programs (77 FR 13764). We decided not to develop such a submission method at that time as the system update required could prove burdensome for providers, especially small practices and those operating proprietary systems, and we instead adopted the batch reporting option which does allow for a more automated process for large groups to submit their data to CMS (77 FR 54089). As noted in the Stage 2 final rule, we will continue to review and analyze the possibility of an electronic system to replace the current manual attestation as CMS continues to work toward program alignment with quality reporting programs, which support electronic submission of CQM data using CEHRT.

After consideration of the comments received, we are finalizing our proposal to maintain attestation as the method of demonstration of meaningful use for the EHR Incentive Programs for 2017 and

subsequent years and the corresponding regulation text at § 495.40.

(1) Meaningful Use Objectives and Measures in 2017 and CEHRT Flexibility in 2017

In the Stage 3 proposed rule (80 FR 16772), in order to allow all providers to successfully transition to Stage 3 of the EHR Incentive Programs for a full year-long EHR reporting period in 2018, we proposed to allow flexibility for the EHR Incentive Programs in 2017. We stated that this transition period would allow providers to establish and test their processes and workflows for Stage 3 of the EHR Incentive Programs prior to 2018. Specifically, for 2017, we proposed that providers may either repeat a year at their current stage or move up stage levels. We also proposed that for 2017, a provider may not move backward in their progression and that providers who participated in Stage 1 in 2016 may choose to attest to the Stage 1 objective and measures, or they may move on to Stage 2 or Stage 3 objectives and measures for an EHR reporting period in 2017. Providers who participated in Stage 2 in 2016 may choose to attest to the Stage 2 objectives and measures or move on to Stage 3 objectives and measures for an EHR reporting period in 2017. However, under no circumstances may providers return to Stage 1.

Finally, we proposed that in 2018, all providers, regardless of their prior participation or the stage level chosen in 2017, would be required to attest to Stage 3 objectives and measures for an EHR reporting period in 2018.

Comment: Many commenters supported allowing providers to choose or not choose Stage 3 in 2017. Commenters noted that the inability to select the stage of participation in prior years was a significant frustration for providers and that allowing choice and flexibility offers providers to the chance to review their performance and attest to the highest level they were able to achieve. However, many commenters were confused by this proposal and how this proposal related to the proposals in the EHR Incentive Programs in 2015 through 2017 proposed rule which would remove the Stage 1 objectives and measures from the program.

Response: We thank the commenters for their insight and reiterate that our intent in the selection of stage for the demonstration of meaningful use is intended to offer greater flexibility for providers. We note that the proposal which includes references to Stage 1 was published prior to the publication of the EHR Incentive Programs in 2015 through 2017 proposed rule and

therefore the proposal to change the stage designations at 80 FR 20352 through 20353 had not yet been made. In section II.B.2.a. of this final rule with comment period, we finalized a set of objectives and measures that all EPs, eligible hospitals, and CAHs must meet for an EHR reporting period in 2015, 2016, and 2017, unless a provider chooses to meet the Stage 3 objectives in 2017. Thus, we will not allow attestation to Stage 1 objectives and measures in 2017 regardless of prior program participation. As stated previously, CMS will not be accepting attestations for an EHR reporting period in 2015 and subsequent years for any objective or measure which has been removed in this final rule with comment period in section II.B.1.b.(4).(b).

After consideration of public comment received, we are finalizing our proposal with modifications to allow providers to attest to the Stage 3 objectives and measures defined at § 495.24 for an EHR reporting period in 2017 instead of the objectives and measures for 2015 through 2017 defined at § 495.22 if they so choose.

(2) Stage and CEHRT Flexibility in 2017

In the Stage 3 proposed rule (80 FR 16772 through 16773), we also proposed to allow providers flexible CEHRT options for an EHR reporting period in 2017 and noted that these options may impact the selection of objectives and measures to which a provider can attest. Specifically, under the CEHRT options for 2017, we proposed that providers would have the option to continue to use EHR technology certified to the 2014 Edition, in whole or in part, for an EHR reporting period in 2017. We noted that providers who use only EHR technology certified to the 2014 Edition for an EHR reporting period in 2017 may not choose to attest to the Stage 3 objectives and measures as those objectives and measures require the support of EHR technology certified to the 2015 Edition. We further explained this proposal at 80 FR 16773 stating that providers using only EHR technology certified in whole or in relevant part to the 2014 Edition certification criteria may attest to the Stage 1 or Stage 2 objectives and measures; and, providers using EHR technology certified in whole or in relevant part to the 2015 Edition certification criteria may elect to attest to the Stage 1 or Stage 2 objectives and measures or to the Stage 3 objectives and measures if they have all the 2015 Edition functionality required to meet all Stage 3 objectives.

We noted that all providers would be required to fully upgrade to EHR technology certified to the 2015 Edition

for the EHR reporting period in 2018. We also reiterated that providers may elect to attest to Stage 3 of the program using EHR technology certified to the 2015 Edition beginning in 2017. Finally, in the Stage 3 proposed rule we stressed that the use of 2011 CEHRT, although an option under the 2014 CEHRT Flexibility final rule (79 FR 52913 through 52914), is not an option under this proposal (80 FR 16773).

We sought comment on this flexibility option including alternate flexibility options and received the following comments on these proposals and our response follows:

Comment: While some commenters expressed skepticism that providers would be ready to attest to Stage 3 in 2017, the majority of commenters were in support of the flexible options for Stage 3 in 2017, especially allowing for the timeline required to fully update to EHR technology certified to the 2015 Edition. While commenters generally expressed concern that most providers may not be ready to progress to Stage 3 in 2017, they supported the proposal to allow providers to select the option for themselves in 2017, which would allow them to work toward that goal but to still successfully meet the requirements of the program in 2017, even if they do not meet the Stage 3 requirements. Additionally, some commenters noted that they would not support an alternate option or policy which required the selection of the Stage 3 objectives and measures in 2017 if the provider has fully implemented EHR technology, but that they agreed that the flexibility to select or not select Stage 3 is a benefit for providers. A number of commenters requested that this flexibility also be extended into 2018 and noted that technology certified to the 2015 Edition may not be ready in time for a reporting period in 2018.

Response: We are committed to working toward the goals outlined for Stage 3 of the EHR Incentive Programs, but we also recognize the need for balance and support of providers in making this transition. We agree that the option of participating in Stage 3 in 2017 should be encouraged but not required. Therefore, we will finalize our proposal to allow providers to choose Stage 3 participation in 2017, and will not require Stage 3 participation if the provider has fully implemented EHR technology certified to the 2015 Edition in 2017.

However, we do reiterate that a provider must have the necessary functions certified to the 2015 Edition in order to successfully demonstrate Stage 3 if they so choose. As discussed in section II.B.3. of this final rule with

comment period, EHR technology certified to the 2015 Edition can support the Stage 2 objectives and measures, but EHR technology certified to the 2014 Edition on its own cannot support all of the Stage 3 objectives and measures. So even though EHR technology certified to the 2015 Edition is not required until 2018, a provider must at least have the functions of CEHRT certified to the 2015 Edition which are required to support the unique Stage 3 measures in order to participate in Stage 3 in 2017. For Stage 3 there are certain EHR technology functions which are not available within the 2014 Edition certification criteria, and if a provider chooses to attest to Stage 3 in 2017 they must use EHR technology modules certified to the 2015 Edition for those functions. These modules and module certification to the 2014 Edition can be used together in many combinations to make up the whole EHR system and meet the definition of CEHRT required for the program. We direct readers to section II.B.3. of this final rule with comment period for further information on the CEHRT definition at § 495.4. See Tables 14, 15, and 16 in section II.B.3. for more information about which modules support specific Stage 3 objectives and measures.

We believe providing flexibility in 2017 will allow for an easier transition and full scale upgrade to EHR technology certified to the 2015 Edition for participation in 2018. We did not propose an extension of this flexibility into 2018 as we are committed to moving toward a single streamlined program to support long term sustainability and reduce the overall complexity for providers participating in the EHR Incentive Programs. We note that, as mentioned in section II.B.1.b.(3). of this final rule with comment period, we are finalizing a 90-day EHR reporting period for providers demonstrating Stage 3 in 2017 to further support providers seeking to move to Stage 3 in 2017.

After consideration of the comments received, we are finalizing a modification to our proposal to allow providers using EHR technology certified to the 2015 Edition, in whole or in part, the option to attest to Stage 3 objectives and measures if they have the relevant CEHRT modules certified to the 2015 Edition certification criteria necessary to support Stage 3. (See Tables 14, 15, 16 in section II.B.3. for more information about which modules support specific Stage 3 objectives and measures.) We further note that CMS will not be accepting attestations for an EHR reporting period in 2015 and subsequent years for any objective or

measure which has been removed in this final rule with comment period in section II.B.1.b.(4).(b). Further we reiterate that certification to the 2011 Edition is no longer valid for use in the EHR Incentive Programs and a provider may not attest to a system with that certification in any year after 2014. Finally, we note that providers using only EHR technology certified to the 2014 Edition may not attest to the Stage 3 objectives and measures for an EHR reporting period in 2017. Therefore, we reiterate the following options for providers for Stage and CEHRT flexibility for an EHR reporting period in 2017:

Providers using only EHR technology certified in whole or in relevant part to the 2014 Edition certification criteria may attest to the objectives and measures of meaningful use defined at § 495.22.

Providers using EHR technology certified in relevant parts to the 2014 Edition certification criteria and EHR technology certified in relevant parts to the 2015 Edition certification criteria may elect to:

- Attest to the objectives and measures at § 495.22.
- Attest to the Stage 3 objectives and measures at § 495.24 if they have the 2015 Edition functionality required to meet the Stage 3 objectives and measures. (See Tables 14, 15, and 16 in section II.B.3. for more information about which modules support specific Stage 3 objectives and measures.)

Providers using only EHR technology certified in whole or in relevant parts to the 2015 Edition certification criteria may elect to:

- Attest to the objectives and measures at § 495.22.
- Attest to the Stage 3 objectives and measures at § 495.24.

We are adopting these policies at § 495.40 with references to the objectives and measures outlined in § 495.22 and § 495.24 for the applicable years.

(3) CQM Flexibility in 2017

In the Stage 3 proposed rule (80 FR 16773), we proposed to allow greater flexibility by proposing to split the use of CEHRT for CQM reporting from the use of CEHRT for the objectives and measures for 2017. This means that providers would be able to separately report CQMs using EHR technology certified to the 2015 Edition even if they use EHR technology certified to the 2014 Edition for the meaningful use objectives and measures for an EHR reporting period in 2017. Providers may also use EHR technology certified to the 2015 Edition for their meaningful use

objectives and measures in 2017 and use EHR technology certified to the 2014 Edition for their CQM reporting for an EHR reporting period in 2017.

For an EHR reporting period in 2017, we proposed that EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016, or a provider may choose to continue to attest to the CQMs established for use in 2017 also using the most recent (2016 version) eCQM electronic specifications.

Similar to our rationale under the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933), we stated that we believe the proposals outlined for attestation in 2017 would allow providers the flexibility to choose the option which applies to their particular circumstances and use of CEHRT (80 FR 16773). We proposed that upon attestation, providers may select one of the proposed options available for their participation year and EHR Edition, and the EHR Incentive Program Registration and Attestation System would then prompt the provider to attest to meeting the objectives, measures, and CQMs applicable under that option. We further proposed that auditors would be provided guidance related to reviewing attestations associated with the options for using CEHRT in 2017, as was done for 2014.

We received comments related to the reporting requirements for CQMs, which are addressed in section II.C. of this final rule with comment period. We also received a number of questions and comments on reporting clinical quality measures for the Medicaid program, which are addressed in section II.C. and II.G. of this final rule with comment period. We received no comments specific to the demonstration of these requirements beyond those previously addressed in section II.D.1.(e).(1). and (2) of this final rule with comment period in relation to the selection of stage, the selection of certified EHR technology, and the overall demonstration of meaningful use in 2017 and subsequent years via attestation.

We are finalizing as proposed the policy to allow providers the flexibility to electronically report CQMs or to attest to CQMs using either EHR technology certified to the 2014 Edition or EHR technology certified to the 2015 Edition, independently of the Edition they use for their objectives and measures for an EHR reporting period in 2017. For further discussion of this final

policy, we direct readers to section II.C. of this final rule with comment period.

2. Alternate Method of Demonstration for Certain Medicaid Providers Beginning in 2015

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20377), we proposed that certain Medicaid EPs would have the option of attesting through the EHR Incentive Program Registration and Attestation system for the purpose of avoiding the Medicare payment adjustment. This alternate method would allow EPs who have previously received an incentive payment under the Medicaid EHR Incentive Program (for either AIU or meaningful use) to demonstrate that they are meaningful EHR users in situations where they fail to meet the eligibility criteria for the Medicaid EHR Incentive Program in a subsequent year.

Comment: Many commenters agreed with our proposal to establish an alternate method of demonstrating meaningful use to allow Medicaid EPs to attest using the CMS registration and attestation system so they can avoid the Medicare payment adjustment. Some commenters questioned whether this would be available prior to February 28, 2016, to allow EPs to attest in cases where the state's attestation system was not ready by the deadline. Some commenters questioned whether attestation information submitted to CMS would be shared with the states.

Response: We intend for this alternate method of demonstrating meaningful use to be available beginning January 1, 2016 for EPs attesting for their EHR reporting period in 2015. However, we proposed this method only for Medicaid EPs who did not meet the eligibility criteria and thus would not be able to attest to the Medicaid EHR Incentive Program for the same year and receive an incentive payment.

We note that Medicaid EPs can avoid the Medicare payment adjustment by successfully demonstrating meaningful use to the state Medicaid agency under the Medicaid EHR Incentive Program, even if it occurs after the Medicare attestation period closes, as long as the attestation is accepted by the state. It would then be the state's responsibility to include that EP in the quarterly report on meaningful users, which we discuss in section II.G. of this final rule with comment period.

Attestations from Medicaid EPs that come through the CMS registration and attestation system will be treated the same as other provider attestations that are submitted to that system for purposes of data sharing. We recognize that states collect, analyze, and use EHR

Incentive Program attestation information for a number of purposes, such as informing other state programs and making policy decisions. However, we will not send information from those attestations to states, consistent with preceding practice.

Comment: A commenter requested clarification regarding the reporting period for EPs who are in the Medicaid EHR Incentive Program and use the alternate method of attestation through the CMS registration and attestation system.

Response: We proposed that EPs using this alternate method would be required to demonstrate meaningful use for the applicable EHR reporting period established for the Medicare EHR Incentive Program, which would depend on the year as well as the EP's prior participation in the program and stage of meaningful use. For example, if the EP is in their first year of demonstrating meaningful use, and the Medicare EHR Incentive Program has a 90-day EHR reporting period for EPs demonstrating meaningful use for the first time in that year, then the EP would use a 90-day EHR reporting period.

We reiterate that an EP's attestation using this alternate method would not constitute a switch from the Medicaid EHR Incentive Program to the Medicare EHR Incentive Program. For the purposes of the Medicaid EHR Incentive Program, an EP's use of this alternate method would be treated the same as if the EP had not attested to meaningful use for that year. For an EP who uses this alternate method, their EHR reporting period in a subsequent year for the Medicaid EHR Incentive Program would be determined without regard to any previous attestations using this alternate method. For example, an EP could still have a 90-day EHR reporting period for the Medicaid EHR Incentive Program for their first year of demonstrating meaningful use even though they had demonstrated meaningful use through this alternate method in a previous year.

Comment: Commenters also asked if CMS would allow this policy for providers who had not yet attested in Medicare or Medicaid as of 2015, given that Medicaid still allows incentive payments for new participants until 2016. A number of commenters requested clarification on what scenarios would providers be allowed to use the alternate attestation and where would it be prohibited, if this did apply for 2015. Specifically, these commenters inquired whether this alternate attestation option is available for providers who are attesting to AIU in

2015 or 2016 and also wish to attest to avoid the Medicare payment adjustment.

Response: We did not propose this option for 2015. However, we understand there may be new participants, and especially newly practicing EPs or new hospitals, for whom this option might be relevant and beneficial. We have considered a number of scenarios that are consistent with our proposed policy which is to allow providers who are working toward achieving meaningful use in the Medicaid EHR Incentive Program to attest under Medicare to avoid the payment adjustment without switching if they are unable to attest under Medicaid for a given year. The option will be available for 2015 under the following scenarios:

- For an EHR reporting period 2015, an EP who has not successfully attested to AIU or meaningful use in either the Medicare or Medicaid program may use the alternate attestation option under the Medicare EHR Incentive Program to avoid a payment adjustment in 2016 and 2017. This EP cannot qualify for an incentive payment under Medicare for 2015 because 2014 is the last first year that an EP may begin receiving Medicare incentive payments under section 1848(o) of the Act. The EP may attest to meaningful use in the Medicaid program for an EHR reporting period in 2016 if they meet the eligibility and other requirements for the Medicaid EHR Incentive Program.

- A provider may not use the alternate attestation option to attest to meaningful use in Medicare to avoid a payment adjustment in conjunction with an attestation for an incentive payment for AIU in the Medicaid program in the same year.

Comment: A number of commenters requested clarification from a systems perspective on how CMS will offer the alternate attestation option and coordinate with states on implementation. Some commenters questioned if CMS is considering an option to allow the states flexibility to develop a no-payment attestation pathway as another option for the providers who are unable to switch but do not meet the thresholds for patient volume required to qualify for a Medicaid incentive payment. Another commenter requested that we describe any operational and technical changes states may need to make to their EHR Incentive Program.

Response: We reiterate that the alternate attestation option for the purpose of avoiding a Medicare payment adjustment will be implemented within the Medicare

registration and attestation system only. As mentioned previously, Medicaid EPs seeking to exercise this option must attest in the Medicare system and in accordance with the requirements for the Medicare EHR Incentive Program in order to successfully demonstrate meaningful use and avoid the Medicare payment adjustment. The only requirement for state support of this proposal is to notify EPs of their eligibility to exercise this alternate option in partnership with CMS provider education and outreach efforts. We will not require additional reporting from states, nor require states to process additional systems changes. We will work with the states to coordinate any necessary information sharing and to monitor real-time use of the alternate attestation option once implemented.

After consideration of the comments received, we are finalizing the proposal for this alternate method of demonstrating meaningful use for certain Medicaid EPs to avoid the Medicare payment adjustment with a modification allowing the alternate attestation for new participants in 2015 as described previously.

3. Data Collection for Online Posting, Program Coordination, and Accurate Payments

We proposed to continue posting Stage 1 and Stage 2 aggregate and individual performance and participation data resulting from the EHR Incentive Programs online regularly for public use. We further noted our intent to potentially publish the performance and participation data on Stage 3 objectives and measures of meaningful use in alignment with quality programs, which utilize publicly available performance data such as Physician Compare.

In addition to the data already being collected under our regulations, as outlined in the Stage 3 proposed rule (80 FR 16774), we proposed to collect the following information from providers to ensure providers keep their information up-to-date through the system of record for their NPI in the NPPES:

- Primary Practice Address (address, city, state zip, country code, etc.).
- Primary Business/Billing Address (address, city, state, zip, country code, etc.).
- Primary License information (for example, provide medical license in at least one state (or territory)).
- Contact Information (phone number, fax number, and contact email address).
- Health Information Exchange Information:

++ Such as DIRECT address required (if available).

++ If DIRECT address is not available, Electronic Service Information is required.

++ If DIRECT address is available, Electronic Service Information is optional in addition to DIRECT address.

We did not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs.

We received the following comments and our response follows:

Comment: We received a number of comments requesting a wider range of publically available data on the Medicare and Medicaid EHR Incentive Programs including cross-referencing Medicaid participation and performance data.

Response: We thank the commenters for their suggestions and will continue to work to promote data transparency and provide data across both programs on provider participation and performance. We refer readers to section II.G.4. of this final rule with comment period for further information on the types of information, CMS is requesting from states to support these efforts and note that we will continue to post data files for public use on the CMS Web site at: www.cms.gov/EHRIncentivePrograms on the data and reports section.

Comment: Some commenters noted the inclusion of the health information exchange information in the providers' record within the NPPES system. A commenter opposed the inclusion, stating that not all providers have a direct address. However, the majority support the proposed enhancements to NPPES as a step in the right direction. Some commenters requested CMS take additional steps to develop some form of "centralized national healthcare provider directory" to support health information exchange and care coordination. Some commenters made further suggestions as to how such a directory should be organized as well as the full extent of exchange information it should contain for each provider.

Response: We note that CMS and ONC are committed to exploring potential models and opportunities to support improved access to the relevant contact information to facilitate health information exchange among providers. We understand that not all providers may have a direct address. Therefore, we proposed to include other exchange information in the system of record as noted in the Stage 3 proposed rule (80 FR 16774). We also understand that not all providers who might participate in health information exchange are participating in the EHR Incentive Programs. However, we believe that this

may be one step in the process to facilitate health information exchange among providers across a wide range of settings.

After consideration of the public comments received, we are finalizing these proposals as proposed.

4. Hospital-Based Eligible Professionals

As noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20378), several hospital associations, individual providers, and other stakeholders have raised concerns with our current definition of a hospital-based EP. Specifically, these stakeholders asserted that the limitation of hospital-based POS codes 21 and 23, covering inpatient and emergency room settings only, does not adequately capture all settings where services might be furnished by a hospital-based EP. They stated that POS 22, which covers an outpatient hospital place of service, is also billed by hospital-based EPs, especially in relation to certain CPT codes. These stakeholders expressed the belief that our current definition of hospital-based EP in the regulations is too narrow and will unfairly subject many EPs who are not hospital-based under our definition, but whom stakeholders would consider to be hospital-based, to the downward payment adjustment under Medicare in 2015. Accordingly, these stakeholders recommended that we consider adding additional place of service codes or settings to the regulatory definition of hospital-based EP. We noted that we appreciate this feedback from stakeholders and requested public comment on our current definition of a hospital-based EP under § 495.4 for the EHR Incentive Programs. We sought public comment on whether additional place of service codes or settings should be included in our definition of a hospital-based EP. In addition, we sought comments on whether and how the inclusion of additional POS codes or settings in our definition of hospital-based EP might affect the eligibility of EPs for the EHR incentive payments under Medicare or Medicaid.

We received the following comments and our response follows:

Comment: A number of commenters on the EHR Incentive Program in 2015 through 2017 proposed rule requested the addition of place of service code (POS 22) to the definition of hospital-based EP. Some of these comments stated that providers may practice across multiple settings and their organizational base may be the hospital outpatient setting, and as a result, they face significant challenges in meeting the requirements of the program. Some

commenters stated that certain physician specialties, such as pathologists, radiologists, and even some hospitalists, have reported challenges with the existing definition and that a change in the definition of hospital-based would provide more clarity for these physicians. A commenter stated that the definition of a hospital-based provider is fundamentally flawed and suggested to define a hospital-based provider as a provider who performs 90 percent or more of their services in place of service 21, 22, and/or 23 (Inpatient Hospital, Outpatient Hospital, and Emergency Room Hospital). A commenter offered an example stating that a cardiac interventionist might not qualify as hospital-based because 90 percent of their services were not billed POS 21 or POS 23 even though they spend 100 percent of their time in the hospital setting. The commenter indicated that the interventionist treats many patients who are admitted as outpatients, reads echocardiograms for the hospital, and has no patient encounters, which are not included in the hospital EHR; but the provider also cannot independently meet the requirements of the program. Some commenters additionally requested that CMS include POS 51 (Inpatient Psychiatric Facility) in addition to POS 22 Observation Services Patients in the hospital-based determination.

On the hospital side, a commenter expressed support for a change in the hospital-based designation because they are currently struggling with the hospital-based designation for the inclusion of services provided in hospital settings by providers who are designated EPs and that the hospital performance on the measures would be higher if these patient encounters were included. The provider recommended that all POS codes should be revisited and the requirements for hospital-based eligibility could be expanded to include all hospital-based POS codes that are rendered in the hospital settings including rehabilitation hospitals and hospital observations, which are otherwise not included in the numerators of their percentages.

Commenters in support of a change were split on when such a change should be implemented. A commenter recommended that CMS change its definition beginning with 2017. Other commenters believe that CMS should retroactively make this correction, and refund physicians who were penalized because of this issue stating physicians who use POS 22 typically are using the hospital-based EHR during the patient

observation period, and should not be penalized.

Many commenters opposed any change in the hospital-based designation. Some commenters stated that this proposal could compromise the purpose of the program. A commenter stated that changing the definition of hospital-based eligible professional at this time in the program could encourage fraud. If an EP who was previously eligible for the incentive would now be ineligible for payment adjustments due to the change, this would be unfair. Some commenters stated that redefining EP by once again including POS 22 in the "hospital" definition would not be reasonable so long as provider-based billing exists. The commenter suggested considering some combination of place of service and NPPE classification which does not exclude the large base of ambulatory providers who bill provider based.

Another commenter stated that including POS 22 in the definition of a hospital-based EP could have major implications for the eligible hospital numerators and denominators. Additionally, the design and implementation of the various parts of a hospital's EHR system would have to be redesigned in order to change the status in addition to changing work flows and training to match that change, which would drastically impact the hospital's ability to meet the measures as well as their overall IT expenditures.

Some commenters stated that adding POS 22 or another change to the designation may undermine the current understanding of the program and would require additional education and guidance to ambulatory providers who have already successfully attested. A commenter stated that they do not support re-classifying services provided in an outpatient hospital (POS 22) setting as hospital-based because of a concern that expanding the hospital-based definition to reduce the number of EPs for EHR Incentives may inhibit continuous hospital investments in ambulatory EHRs. The commenter noted that the ambulatory EHR space is an important component to the overall HIT ecosystem and that CMS should encourage investment in this area by excluding outpatient services from the hospital-based calculation. The commenter stated that the current definition of a hospital-based provider is consistent with the hospital's payment calculation, which is based on inpatient discharges and emergency department services, and is consistent with the collection of EHR Incentive Program information for hospitals. The commenter continued by stating that if

CMS included POS 22 services in the hospital-based provider definition, CMS would need to revisit whether the inclusion of these services affects the hospital payment calculation and collection of EHR Incentive Program encounters for hospitals. Another commenter expressed a similar concern that changing the hospital-based designation may have unintended consequences on the hospital payment calculation, necessitating adjustments to all payments made to date if CMS chooses to make a change to the definition of hospital based.

Other commenters stated this is a very complex issue and sought further clarification on the impact of a potential change, noting organizations that have many subspecialists who see patients in the hospital outpatient setting using an office or ambulatory workflow and that these providers may be required to bill with POS 22 due to the physical location of their offices. The commenter stated that the majority of these EPs are currently meeting the requirements of the program and will continue to practice medicine in the same manner going forward. However, the commenter also noted that there are EPs who are truly "hospital-based," such as hospitalists, who are currently being held to the same standard as ambulatory providers, even though their workflow is not conducive to easily meeting such standards. The commenter then recommended that CMS allow providers who see both inpatient and ambulatory patients with a significant volume to choose whether they want to be excluded from the program or continue to participate as an individual eligible professional.

Other recommendations from commenters included a mention of hardship exceptions for POS 22-related issues, a suggestion to allow EPs the right, in an expedited fashion, to petition for a change in their hospital-based status when there is a material change in their organizational affiliation (that is, a physician leaving a hospital-based practice to join an outpatient physician practice), excluding patient encounters in POS 21 and POS 23 for an EP, and excluding the POS 21 and POS 23 encounters from Medicare payment adjustment.

Response: The scenarios and examples described by the commenters are consistent with those we have heard from providers previously. However, we are concerned that there does not seem to be an identifiable factor that has changed since the program began and caused EPs who were previously designated hospital-based to be designated otherwise. In addition, the

comments both in support of and opposing a revision to the hospital-based EP definition show the wide diversity of providers who may have services billed under a different POS who fall on both sides of the argument for and against an amendment of the definition. We see no method to modify the current definition to clearly identify EPs for whom inclusion in the definition might be reasonable and those for whom inclusion in the definition might be inappropriate. Further, we are concerned that any blanket redesignation of EPs in certain settings would result in the exclusion of patient encounters in those settings being captured in an EHR. Without a clear rationale for a change, and without a clear definition to change to, we cannot proceed to change the definition of hospital-based EP at this time.

Therefore, we are not finalizing changes to the definition of hospital-based EP at this time. We will continue to consider this issue in the future as we explore program requirements for the MIPS.

5. Interaction With Other Programs

We proposed no changes to the ability of providers to participate in the Medicare and Medicaid EHR Incentive Programs and other CMS programs. We continue to work on aligning the data collection and reporting of the various CMS programs, especially in the area of clinical quality measurement. See sections II.C. of this final rule with comment period for the policies and requirements for CQM reporting.

E. Payment Adjustments and Hardship Exceptions

Sections 4101(b) and 4102(b) of the HITECH Act, amending sections 1848, 1853, and 1886 of the Act, require reductions in payments to EPs, eligible hospitals, and CAHs that are not meaningful users of certified EHR technology, beginning in CY 2015 for EPs, FY 2015 for eligible hospitals, and in cost EHR reporting periods beginning in FY 2015 for CAHs.

1. Statutory Basis for Payment Adjustments and Hardship Exceptions

a. Statutory Basis for Payment Adjustments and Hardship Exceptions for Eligible Professionals (EPs)

Section 1848(a)(7) of the Act provides for payment adjustments, effective for CY 2015 and subsequent years, for EPs as defined in § 495.100, who are not meaningful EHR users during the relevant EHR reporting period for the year. Section 1848(a)(7) of the Act provides that beginning in 2015, if an EP is not a meaningful EHR user for the

EHR reporting period for the year, then the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the “applicable percent” of the fee schedule amount that would otherwise apply.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) was enacted on April 16, 2015, after the publication of the Stage 3 proposed rule and the EHR Incentive Program in 2015 through 2017 proposed rule. Section 101(b)(1)(A) of MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment for EPs at the end of CY 2018. Section 101(c) of MACRA added section 1848(q) of the Act requiring the establishment of a MIPS, which would incorporate certain existing provisions and processes related to meaningful use. The term “applicable percent” is defined in section 1848(a)(7)(A)(ii) of the Act, as amended by section 101(b)(1)(A) of MACRA, as: (I) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment [if the EP was not a successful electronic prescriber] under section 1848(a)(5) of the Act for 2014, 98 percent); (II) for 2016, 98 percent; and (III) for 2017 and 2018, 97 percent.

In addition, section 1848(a)(7)(A)(iii) of the Act, as amended by section 101(b)(1)(A) of MACRA, provides that if, for CY 2018, the Secretary finds the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year.

Section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP who is not a meaningful EHR user for the EHR reporting period for the year from the application of the payment adjustment if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient internet access. The exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years.

We established regulations implementing these statutory provisions under § 495.102. We refer readers to the final rules for Stages 1 and 2 (75 FR

44447 through 44448 and 77 FR 54093 through 54102) for more information.

b. Statutory Basis for Payment Adjustments and Hardship Exceptions for Eligible Hospitals

Section 1886(b)(3)(B)(ix)(I) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to the applicable percentage increase to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the associated EHR reporting period for a payment adjustment year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, for FY 2015 and each subsequent fiscal year, an eligible hospital that is not “a meaningful EHR user . . . for an EHR reporting period” will receive a reduced update to the IPPS standardized amount. This reduction applies to “three-quarters of the percentage increase otherwise applicable” prior to the application of statutory adjustments under sections 1886(b)(3)(B)(viii), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act, or three-quarters of the applicable market basket update. The reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user will be “33 $\frac{1}{3}$ percent for FY 2015, 66 $\frac{2}{3}$ percent for FY 2016, and 100 percent for FY 2017 and each subsequent FY.” In other words, for eligible hospitals that are not meaningful EHR users, the Secretary must reduce the applicable percentage increase (prior to the application of other statutory adjustments) by 25 percent (33 $\frac{1}{3}$ of 75 percent) in FY 2015, 50 percent (66 $\frac{2}{3}$ percent of 75 percent) in FY 2016, and 75 percent (100 percent of 75 percent) in FY 2017 and subsequent years. Section 4102(b)(1)(B) of the HITECH Act also provides that the reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase for a subsequent fiscal year.

Section 1886(b)(3)(B)(ix)(II) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that the Secretary may, on a case-by-case basis, exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year if the Secretary determines that requiring such hospital to be a meaningful EHR user will result in a significant hardship, such as in the case of a hospital in a rural area without sufficient internet access. This section also provided that such determinations are subject to annual renewal and that in no case may

a hospital be granted an exception for more than 5 years.

Section 412.64(d) sets forth the adjustment to the percentage increase in the market basket index for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015.

We established regulations implementing these statutory provisions under § 412.64. We refer readers to the final rules for Stages 1 and 2 (75 FR 44460 and 77 FR 54102 through 54109) for more information.

c. Statutory Basis for Payment Adjustments and Hardship Exceptions for CAHs

Section 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act to include an adjustment to a CAH's Medicare reimbursement for inpatient services if the CAH is not a meaningful EHR user for an EHR reporting period. The adjustment will be made for cost EHR reporting periods that begin in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act provide that, if a CAH does not demonstrate meaningful use of CEHRT for an applicable EHR reporting period, then for a cost EHR reporting period beginning in FY 2015, the CAH's reimbursement shall be reduced from 101 percent of its reasonable costs to 100.66 percent of reasonable costs. For a cost EHR reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost EHR reporting period beginning in FY 2017 and each subsequent fiscal year, its reimbursement would be reduced to 100 percent of reasonable costs. We established regulations implementing these statutory provisions under § 413.70. We refer readers to the final rules for Stages 1 and 2 (75 FR 44464 and 77 FR 54110 through 54111) for more information.

However, as provided for eligible hospitals, a CAH may, on a case-by-case basis, be granted an exception from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that a significant hardship exists, such as in the case of a CAH in a rural area without sufficient internet access. However, in no case may a CAH be granted this exception for more than 5 years.

2. EHR Reporting Period for a Payment Adjustment Year

In the EHR Incentive Programs in 2015 through 2017 proposed rule and the Stage 3 proposed rule, we proposed

several changes to the definition of the EHR reporting period for a payment adjustment year for EPs, eligible hospitals, and CAHs at § 495.4, in connection with other proposals made in those rules. For an explanation of these proposals, we refer readers to 80 FR 16774 through 16779 and 80 FR 20378 through 20381.

a. Changes to the EHR Reporting Period for a Payment Adjustment Year for EPs

As follows is a summary of the comments received on the proposals for the EHR reporting period for a payment adjustment year for EPs (80 FR 16774 through 16779 and 80 FR 20378 through 20381):

Comment: We received a few comments supporting the proposed deadline of February 29, 2016 for new participants to attest in order to avoid a payment adjustment in CY 2016 in light of the other program changes proposed in the rule. Many commenters expressed concern with our proposal to remove the 90-day EHR reporting period for new participants. They noted that this will create an enormous barrier for new entrants and will likely deter participation in the program and others stated that new entrants need time to install and learn to use technology before beginning their first EHR reporting period. Commenters also requested an extended deadline ranging from 2 months to 6 months additional time in 2016 for attestations for EHR reporting periods in 2015. Additionally some commenters requested clarification of the early attestation deadlines for new participant EPs in 2016 and 2017.

Response: We thank you for your comments and support. For discussion of the attestation deadlines for EPs we direct readers to section II.D. of this final rule with comment period. Regarding the comments on the attestation deadlines, we proposed that for EPs demonstrating meaningful use for the first time in 2016, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2016 and applies for purposes of the payment adjustments in CYs 2017 and 2018. To avoid the payment adjustment in CY 2017, the 90-day period must occur within the first three quarters of CY 2016 and the EP must attest by October 1, 2016. We refer readers to 80 FR 20380 through 20381 of the EHR Incentive Programs in 2015 through 2017 proposed rule for additional information.

We agree with the concerns expressed by commenters regarding our proposal to discontinue the 90-day EHR reporting period for a payment adjustment year

for new participants who attest under Medicare beginning in 2017. We agree that a full year EHR reporting period could be a barrier for new entrants and could deter participation in the program especially as new entrants need time to install and learn to use technology before beginning their first EHR reporting period. However, we maintain that it is important to move all providers to the same EHR reporting period to simplify the program. So in 2018 all providers will attest to the Stage 3 definition of meaningful use for an EHR reporting period of the entire calendar year, with a limited exception for Medicaid providers who demonstrated AIU prior to 2017 and are demonstrating meaningful use for the first time. For these reasons, we will adopt a final policy that for EPs demonstrating meaningful use for the first time in 2017 under Medicare or Medicaid, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2017 and applies for purposes of the payment adjustments in CY 2018. To avoid the payment adjustment in CY 2018, the 90-day period must occur within the first three quarters of CY 2017 and the EP must attest by October 1, 2017.

Comment: Some commenters noted that new participants in 2018 would be moving to Stage 3 and should have a 90 day EHR reporting period for that purpose, not just in Medicaid but also in Medicare. Other commenters stated that any provider in their first year, and all providers in the first year of a new stage, should have a 90-day reporting period.

Response: We do not believe a 90-day EHR reporting period is necessary for new participants in 2018 as discussed in section II.B.1.b.(3).(a). of this final rule with comment period. However, we note that we are offering additional flexibility for any provider, new or returning, who elects to participate in Stage 3 in 2017 which we believe is a fair solution to support these providers' efforts to move forward in the program. As noted in section II.E.2. of this final rule with comment period, we are adopting a policy for EPs in the Medicaid program, and for eligible hospitals and CAHs who demonstrate Stage 3 in 2017, allowing a 90-day EHR reporting period. We are adopting this policy based on public comment received (as discussed in section II.B.1.b.(3)(c) of this final rule with comment period) in relation to the EHR reporting period for 2017 in order to allow these providers adequate time to upgrade to the required 2015 Edition technology and to encourage providers to select the option to participate in the

Stage 3 objectives and measures which support our long term goals. For Medicaid EPs, and for new participants in Medicare and Medicare, this 90-day EHR reporting period for Stage 3 would also apply for the purposes of avoiding the payment adjustment in 2019 for returning participants and for the payment adjustment in 2018 for new participants who attest to Stage 3 prior to October 1, 2017.

For Medicare EPs, we note that the EHR reporting period for a payment adjustment year for returning participants in 2017 and for all Medicare EPs in 2018 and subsequent years will be established through future rulemaking in association with the MIPS program discussed further in the comments and responses immediately following.

Comment: We received a number of comments requesting clarification of how the policies proposed in the EHR Incentive Program in 2015 through 2017 and Stage 3 proposed rules are affected by recent legislation modifying the HITECH Act provisions for payment adjustments for eligible professionals.

Response: As noted previously, section 101(b)(1)(A) of MACRA amended section 1848(a)(7)(A) of the Act to sunset the EHR Incentive Program payment adjustment for EPs at the end of CY 2018. Thus, we are not finalizing the proposal (80 FR 16775) that for all EPs beginning with the CY 2019 payment adjustment year, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year (for example, CY 2017 as the EHR reporting period for the CY 2019 payment adjustment year). We are also not finalizing the proposed limited exception for EPs demonstrating meaningful use under the Medicaid EHR Incentive Program for the first time (80 FR 16775). The reason we are not

finalizing these proposals is because CY 2018 will be the last payment adjustment year for EPs under section 1848(a)(7)(A) of the Act, as amended by section 101(b)(1)(A) of MACRA. As noted previously, section 1848(q) of the Act, as added by section 101(c) of MACRA, requires the establishment of MIPS, which would incorporate certain existing provisions and processes related to meaningful use. We intend to implement MIPS through future rulemaking, which among other things would address the effect on Medicare Physician Fee Schedule payments in CY 2019 and subsequent years for certain EPs who are not meaningful EHR users for an applicable performance period. We encourage readers to review and respond to our request for information titled "Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models" published in the October 1, 2015 **Federal Register** (80 FR 59102).

After consideration of the public comments, we are finalizing the following changes to the EHR reporting period for a payment adjustment year for EPs as proposed, with a modification for 2017. In CY 2015, the EHR reporting period for a payment adjustment year for EPs who have not successfully demonstrated meaningful use in a prior year ("new participants") is any continuous 90-day period in CY 2015. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustments in CYs 2016 and 2017 if the EP successfully attests by February 29, 2016.

In CY 2015, the EHR reporting period for a payment adjustment year for EPs

who have successfully demonstrated meaningful use in a prior year ("returning participants") is any continuous 90-day period in CY 2015. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2017 if the EP successfully attests by February 29, 2016.

In CY 2016, the EHR reporting period for a payment adjustment year for EPs who are new participants is any continuous 90-day period in CY 2016. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2017 if the EP successfully attests by October 1, 2016, and will avoid the payment adjustment in CY 2018 if the EP successfully attests by February 28, 2017.

In CY 2016, the EHR reporting period for a payment adjustment year for EPs who are returning participants is the full CY 2016. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2018 if the EP successfully attests by February 28, 2017.

In CY 2017, the EHR reporting period for a payment adjustment year for EPs who are new participants is any continuous 90-day period in CY 2017. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2018 if the EP successfully attests by October 1, 2017.

We have revised the definition of "EHR reporting period for a payment adjustment year" under § 495.4 to reflect these final policies. Table 18 contains a summary of the final policies.

TABLE 18—EHR REPORTING PERIODS AND RELATED PAYMENT ADJUSTMENT YEARS FOR EPS

2015			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in CY 2016	Applies to avoid a payment adjustment in CY 2017
EPs who have not successfully demonstrated meaningful use in a prior year (new participants).	Any continuous 90-day period in CY 2015.	Yes, if EP successfully attests by February 29, 2016.	Yes, if EP successfully attests by February 29, 2016.
EPs who have successfully demonstrated meaningful use in a prior year (returning participants).	Any continuous 90-day period in CY 2015.	No	Yes, if EP successfully attests by February 29, 2016.
2016			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in CY 2017	Applies to avoid a payment adjustment in CY 2018.
EP new participants	Any continuous 90-day period in CY 2016.	Yes, if EP successfully attests by October 1, 2016.	Yes, if EP successfully attests by February 28, 2017.
EP returning participants	CY 2016	No	Yes, if successfully attest by February 28, 2017.
2017			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in CY 2018	Applies to avoid a payment adjustment in CY 2019
EP new participants	Any continuous 90-day period in CY 2017.	Yes, if EP successfully attests by October 1, 2017.	N/A.
EP returning participants	N/A	N/A	N/A.
Medicaid EP returning participants demonstrating Stage 3.	Any continuous 90-day period in CY 2017.	No	Yes, if successfully attest by February 28, 2018.

b. Changes to the EHR Reporting Period for a Payment Adjustment Year for Eligible Hospitals

As follows is a summary of the comments received on the proposals for the EHR reporting period for a payment adjustment year for eligible hospitals (80 FR 16776 through 16778 and 80 FR 20380 through 20381):

Comment: We received a number of comments stating that new participant eligible hospitals should be allowed to attest prior to January 1, 2016 in order to earn an incentive payment and avoid the Medicare payment adjustment for 2016. We received comments in support of the proposed changes to the EHR reporting period for a payment adjustment year to allow for greater flexibility and more time for eligible hospitals to work toward successful demonstration of meaningful use.

Response: We thank the commenters and note that the attestation period will be open for all providers in January of 2016 to attest for an EHR reporting period in 2015.

Comment: Some commenters agreed with the proposal as described to align EHR reporting periods for the purpose of future payment adjustments and endorsed the proposal to continue with the current structure for these components. Some comments also supported a single deadline for new

participants to attest to avoid the payment adjustments in 2017.

Response: We appreciate the commenters' feedback and support. We strongly believe this will simplify the EHR Incentive Program and further our goal to align reporting requirements under the EHR Incentive Program and the reporting requirements for various CMS quality reporting programs, to respond to stakeholders who cited difficulty with following varying reporting requirements, and to simplify HHS system requirements for data capture.

Comment: Some commenters expressed concerns about our proposal to require first-time participants to fulfill an EHR reporting period 2 years in advance of the payment adjustment year. They believe that this policy change is unnecessarily confusing and unfairly penalizes first-time participants. They recommended that CMS retain its current policy to allow first-time participants to avoid a penalty in the subsequent year.

Some commenters noted that new participants in 2018 would be moving to Stage 3 and should have a 90 day EHR reporting period for that purpose. Other commenters stated that any provider in their first year, and all providers in the first year of a new stage, should have a 90 day reporting period.

Response: We recognize the commenters' concerns, and for the reasons stated in section II.E.2.a with regard to new participant EPs in 2017, we will adopt a final policy that for eligible hospitals demonstrating meaningful use for the first time in 2017 under Medicare or Medicaid, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2017 and applies for purposes of the payment adjustments in FY 2018. To avoid the payment adjustment in FY 2018, the 90-day EHR reporting period must occur within the first three quarters of CY 2017 and the eligible hospital must attest by October 1, 2017.

However, we will adopt a final policy beginning in 2018 to require eligible hospitals (new participants and returning participants) that attest to meaningful use under Medicare to complete a full CY EHR reporting period that is 2-years before the payment adjustment year. We are adopting a limited exception of a 90-day EHR reporting period the year that is 2 years before the payment adjustment year for Medicaid participants demonstrating meaningful use for the first time that previously demonstrated AIU prior to 2017 to allow these providers to earn an incentive payment in the Medicaid program for 2018 without receiving an penalty in the Medicare program.

We disagree that the change to a full-year EHR reporting period unfairly impacts new participant. We note that the prior exception to allow a 90-day EHR reporting period favors new participants over returning participants who have no such opportunity to avoid a payment adjustment in the subsequent year. We further note that new participants could have chosen to begin the program at any time since 2011 unless they are newly practicing providers who are already afforded a hardship exception from the penalty.

After consideration of the public comments, we are finalizing the following changes to the EHR reporting period for a payment adjustment year for eligible hospitals as proposed, with a modification for the EHR reporting period in 2017. For the reasons stated in section II.E.2.a. of this final rule with comment period for Medicaid EPs participating in Stage 3 in 2017, we are finalizing a similar policy for eligible hospitals to establish a 90-day EHR reporting for Stage 3 participants in 2017 for the purposes of avoiding the payment adjustment in 2019 for returning participants and for the payment adjustment in 2018 for new participants who attest to Stage 3 prior to October 1, 2017. For further discussion of the policy related to the EHR reporting period in 2017 we direct readers to section II.B.1.b.(3).iii. of this final rule with comment period.

In CY 2015, the EHR reporting period for a payment adjustment year for eligible hospitals that have not successfully demonstrated meaningful use in a prior year (new participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FYs 2016 and 2017 if the eligible hospital successfully attests by February 29, 2016.

In CY 2015, the EHR reporting period for a payment adjustment year for eligible hospitals that have successfully demonstrated meaningful use in a prior year (returning participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. An eligible hospital that successfully demonstrates

meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the eligible hospital successfully attests by February 29, 2016.

In CY 2016, the EHR reporting period for a payment adjustment year for eligible hospitals that are new participants is any continuous 90-day period in CY 2016. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the eligible hospital successfully attests by October 1, 2016, and will avoid the payment adjustment in FY 2018 if the eligible hospital successfully attests by February 28, 2017.

In CY 2016, the EHR reporting period for a payment adjustment year for eligible hospitals that are returning participants is the full CY 2016. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2018 if the eligible hospital successfully attests by February 28, 2017.

In CY 2017, the EHR reporting period for a payment adjustment year for eligible hospitals that are new participants is any continuous 90-day period in CY 2017. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2018 if the eligible hospital successfully attests by October 1, 2017 and will avoid the payment adjustment in FY 2019 if the eligible hospital successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for eligible hospitals that are demonstrating Stage 3 is any continuous 90-day period in CY 2017. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2019 if the eligible hospital successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for eligible hospitals that are returning

participants and are not demonstrating Stage 3, is the full CY 2017. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2019 if the eligible hospital successfully attests by February 28, 2018.

Beginning in CY 2018, the EHR reporting period for a payment adjustment year for eligible hospitals is the entire calendar year that is two years before the payment adjustment year. For example, CY 2018 is the EHR reporting period for the FY 2020 payment adjustment year. The exception to this general rule is for eligible hospitals that successfully demonstrated AIU under the Medicaid EHR Incentive Program for a payment year prior to 2017 and are demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program in the calendar year that is two years before the payment adjustment year. For those eligible hospitals, the same 90-day EHR reporting period used for the Medicaid incentive payment will also apply for purposes of the Medicare payment adjustment year 2 years after the calendar year in which the eligible hospital demonstrates meaningful use. For example, if an eligible hospital has never successfully demonstrated meaningful use in a prior year and demonstrates under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in CY 2018, the EHR reporting period for the Medicaid incentive payments any continuous 90-day period within CY 2018, and the same 90-day period also serves as the EHR reporting period for the FY 2020 payment adjustment year under Medicare. An eligible hospital that successfully demonstrates meaningful use for the relevant period and satisfies all other program requirements will avoid the payment adjustment in the relevant year if the eligible hospital successfully attests by the date specified by CMS.

We have revised the definition of "EHR reporting period for a payment adjustment year" under § 495.4 to reflect these final policies. Table 19 contains a summary of the final policies, although it does not include years beyond 2018.

TABLE 19—EHR REPORTING PERIODS AND RELATED PAYMENT ADJUSTMENT YEARS FOR ELIGIBLE HOSPITALS

2015			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2016	Applies to avoid a payment adjustment in FY 2017
Eligible hospitals that have not successfully demonstrated meaningful use in a prior year (new participants).	Any continuous 90-day period from October 1, 2014 through December 31, 2015.	Yes, if eligible hospital successfully attests by February 29, 2016.	Yes, if eligible hospital successfully attests by February 29, 2016.
Eligible hospitals that have successfully demonstrated meaningful use in a prior year (returning participants).	Any continuous 90-day period from October 1, 2014 through December 31, 2015.	No	Yes, if eligible hospital successfully attests by February 29, 2016.
2016			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2017	Applies to avoid a payment adjustment in FY 2018
Eligible hospital new participants ...	Any continuous 90-day period in CY 2016.	Yes, if eligible hospital successfully attests by October 1, 2016.	Yes, if eligible hospital successfully attests by February 28, 2017.
Eligible hospital returning participants.	CY 2016	No	Yes, if eligible hospital successfully attests by February 28, 2017.
2017			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2018	Applies to avoid a payment adjustment in FY 2019
Eligible hospital new participants ...	Any continuous 90-day period in CY 2017.	Yes, if eligible hospital successfully attests by October 1, 2017.	Yes, if eligible hospital successfully attests by February 28, 2018.
Eligible hospital Stage 3 participants.	Any continuous 90-day period in CY 2017.	No for returning participants	Yes, if eligible hospital successfully attests by February 28, 2018.
Eligible hospital returning participants.	CY 2017	No	Yes, if eligible hospital successfully attests by February 28, 2018.
2018			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2019	Applies to avoid a payment adjustment in FY 2020
Eligible hospital new participants ...	CY 2018	No	Yes, if eligible hospital successfully attests by February 28, 2019.
Eligible hospital Medicaid exception.	The continuous 90-day EHR reporting period for the Medicaid incentive payment in CY 2018.	No	Yes, if eligible hospital successfully attests by February 28, 2019.
Eligible hospital returning participants.	CY 2018	No	Yes, if eligible hospital successfully attests by February 28, 2019.

c. Changes to the EHR Reporting Period for a Payment Adjustment Year for CAHs

As follows is a summary of the comments received on the proposals for the EHR reporting period for a payment adjustment year for CAHs (80 FR 16777 through 16779 and 80 FR 20381):

Comment: We received a number of comments stating that CAHs should be allowed to attest in 2015 if they are demonstrating meaningful use for the first time in order to earn an incentive payment and avoid the 2015 payment adjustment. We further received

requests for clarification of whether the early attestation deadlines apply for CAHs in order to avoid future payment adjustments as first time participants.

Response: As noted in section II.D. of this final rule with comment period, some new participant CAHs have already attested to meaningful use for an EHR reporting period in 2015. The early attestation deadlines do not apply to CAHs because of the alignment of the EHR reporting period with the payment adjustment year and the use of the cost report reconciliation process to reduce a CAH's Medicare reimbursement for

reasonable costs incurred if the CAH does not successfully demonstrate meaningful use for the applicable EHR reporting period. Furthermore, for the reasons stated in section II.E.2.a. of this final rule with comment period with regard to new participant EPs in 2017, we will adopt a final policy that for CAHs demonstrating meaningful use for the first time in 2017 under Medicare or Medicaid, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2017 and applies for purposes of the payment adjustments in FY 2017.

We will also adopt a final policy beginning in 2018 to require CAH (new participants and returning participants) that attest to meaningful use under Medicare to complete a full CY EHR reporting period that is the payment adjustment year. We are adopting a limited exception of a 90-day EHR reporting period within the calendar year that is the payment adjustment year for Medicaid CAH participants demonstrating meaningful use for the first time that previously demonstrated AIU prior to 2017 to allow these providers to earn an incentive payment in the Medicaid program for 2018 without receiving a penalty in the Medicare program.

After consideration of the public comments, we are finalizing the following changes to the EHR reporting period for a payment adjustment year for CAHs as proposed, with a modification for the EHR reporting period in 2017. For the reasons stated in section II.E.2.a. of this final rule with comment period for Medicaid EPs for Stage 3 in 2017, we are finalizing a similar policy for CAHs to establish a 90-day EHR reporting for Stage 3 participants in 2017 for the purposes of avoiding the payment adjustment for FY 2017. For further discussion of the policy related to the EHR reporting period in 2017 we direct readers to section II.B.1.b.(3).iii. of this final rule with comment period.

In CY 2015, the EHR reporting period for a payment adjustment year for CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2015 if the CAH successfully attests by February 29, 2016.

In CY 2015, the EHR reporting period for a payment adjustment year for CAHs that have successfully demonstrated meaningful use in a prior year (returning participants) is any continuous 90-day period beginning on October 1, 2014 and ending on

December 31, 2015. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2015 if the CAH successfully attests by February 29, 2016.

In CY 2016, the EHR reporting period for a payment adjustment year for CAHs that are new participants is any continuous 90-day period in CY 2016. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2016 if the CAH successfully attests by February 28, 2017.

In CY 2016, the EHR reporting period for a payment adjustment year for CAHs that are returning participants is the full CY 2016. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2016 if the CAH successfully attests by February 28, 2017.

In CY 2017, the EHR reporting period for a payment adjustment year for CAHs that are new participants is any continuous 90-day period in CY 2017. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the CAH successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for CAHs that are demonstrating Stage 3 is any continuous 90-day period in CY 2017. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the CAH successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for CAHs that are returning participants and are not demonstrating Stage 3, is the full CY 2017. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the CAH

successfully attests by February 28, 2018.

Beginning in CY 2018, the EHR reporting period for a payment adjustment year for CAHs is the calendar year that begins on the first day of the second quarter of the federal fiscal year that is the payment adjustment year. For example, in order for a CAH to avoid application of the adjustment to its reasonable costs incurred in a cost reporting period that begins in FY 2018, the CAH must demonstrate it is a meaningful EHR user for an EHR reporting period of the full CY 2018. The exception to this general rule is for CAHs that successfully demonstrated AIU under the Medicaid EHR Incentive Program for a payment year prior to 2017 and are demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program in the calendar year that begins on the first day of the second quarter of the federal fiscal year that is the payment adjustment year. For those CAHs, the same 90-day EHR reporting period used for the Medicaid incentive payment will also apply for purposes of the Medicare payment adjustment year. For example, if a CAH has never successfully demonstrated meaningful use in a prior year and demonstrates under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in CY 2018, the EHR reporting period for the Medicaid incentive payment is any continuous 90-day period within CY 2018, and the same 90-day period also serves as the EHR reporting period for the FY 2018 payment adjustment year under Medicare. A CAH that successfully demonstrates meaningful use for the relevant period and satisfies all other program requirements will avoid the payment adjustment in the relevant year if the CAH successfully attests by the date specified by CMS.

We have revised the definition of "EHR reporting period for a payment adjustment year" under § 495.4 to reflect these final policies. Table 20 contains a summary of the final policies, although it does not include years beyond 2018.

TABLE 20—EHR REPORTING PERIODS AND RELATED PAYMENT ADJUSTMENT YEARS FOR CAHS

2015		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2015
CAHs that have not successfully demonstrated meaningful use in a prior year (new participants).	Any continuous 90-day period from October 1, 2014 through December 31, 2015	Yes, if CAH successfully attests by February 29, 2016.
CAHs that have successfully demonstrated meaningful use in a prior year (returning participants).	Any continuous 90-day period from October 1, 2014 through December 31, 2015	
2016		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2016
CAH new participants	Any continuous 90-day period in CY 2016	Yes, if CAH successfully attests by February 28, 2017.
CAH returning participants	CY 2016.	
2017		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2017
CAH new participants	Any continuous 90-day period in CY 2017	Yes, if CAH successfully attests by February 28, 2018.
CAH Stage 3 participants	Any continuous 90-day period in CY 2017	
CAH returning participants	CY 2017.	
2018		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2018
CAH new participants	Any continuous 90-day period in CY 2018	Yes, if CAH successfully attests by February 28, 2018.
CAH returning participants	CY 2018.	

3. Hardship Exceptions

As stated previously, sections 1848(a)(7)(B) and 1886(b)(3)(B)(ix)(II) of the Act provide the Secretary with discretionary authority to exempt, on a case by case basis, a provider from the application of the Medicare payment adjustment if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship. We have established various types of hardship exceptions for which providers may apply as well as deadlines for application. For more information, we refer readers to the Stage 2 final rule at 77 FR 54093 through 54113.

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20381), we proposed no changes to the types of hardship exceptions available to EPs, eligible hospitals, and CAHs. Further, we proposed no changes to the existing hardship exception process and timelines under our regulations.

In the Stage 3 proposed rule we proposed no changes to the types of exceptions previously finalized for EPs, eligible hospitals or CAHs (80 FR 16775,

80 FR 16777 and 80 FR 16779), nor did we propose any new types of exceptions for 2017 and subsequent years. Accordingly, we proposed that the exceptions continue as previously finalized. As follows is a summary of the comments received for hardship exceptions:

Comment: We received a number of comments requesting an extension of the hardship exception application deadline from July 1 to December 31 of the year proceeding the payment adjustment year. A commenter noted that CMS allowed for providers to apply for a hardship exception in November of the year proceeding the payment adjustment year in 2014 and that such a provision should be possible in every year.

Response: We thank the commenters for their suggestions but disagree with their assessment. The extension of the hardship exception application deadline to later in the year is both unnecessary and a significant burden for the program and for those providers whose claims may need to be reprocessed. We note that the expedited processing and reprocessing of claims represents a

significant cost which should be avoided where feasible. Furthermore, if the applicable EHR reporting period for a payment adjustment year occurs 2 years before the payment adjustment year, providers that fail to demonstrate meaningful use for that period will be aware of their status well in advance of the deadline for applying for a hardship exception, and thus no such extension is necessary. New participants in the program who are uncertain of their ability to meet the requirements of the program in a given year may apply for a hardship exception even if they later find they are able to successfully attest in the program. The provider is not required to withdraw the hardship exception application, and the application does not affect their subsequent attestation for meaningful use. Therefore, we do not believe a general extension of the hardship exception application deadline is necessary, although we may consider extensions in exceptional circumstances.

Comment: A large number of commenters requested that CMS add

new hardship exception categories for the EHR Incentive Programs. Commenters believed that there should be additional exception categories, especially for providers experiencing issues with certified EHR technology and EHR vendors; providers who are unable to achieve meaningful use due to the all-or-nothing approach; providers practicing in multiple locations or who have transitioned between locations; providers who are beyond retirement age; specialty providers; providers who are new to the EHR Incentive Program and have not yet achieved meaningful use; providers who see observation patients; and fellows. Commenters believe providers who fall into any of these categories have significant reasons to be included in the list of those who qualify for hardship exceptions and should not receive payment adjustments.

Response: We note that providers may already apply for a hardship exception under the extreme and uncontrollable circumstances category if they experience issues with a vendor product including issues related to upgrades and transitions from one product to another. In addition, we note that new participants have the same ability to apply for a hardship exception as any other provider. We also established hardship exception categories for newly practicing EPs, new eligible hospitals, and new CAHs. We do not believe there are acceptable standards to establish a category based on age or potential retirement status given the wide variation among providers and potential influencing factors. Finally, we believe that the existing categories are broad and comprehensive enough to cover many different circumstances where meeting the program requirements would be a significant hardship due to circumstances outside the control of the provider and related to their particular practice or organization.

Comment: Some commenters requested clarification around whether the 5-year limitation for hardship exceptions will be applicable to providers with PECOS specialties of diagnostic radiology (30), nuclear medicine (36), interventional radiology (94), anesthesiology (05), and pathology (22). Commenters believed these providers might retain the same PECOS specialty code for more than 5 years.

Response: Under section 1848(a)(7)(B) of the Act, the Secretary has discretion, on a case-by-case basis, to exempt an EP from the Medicare payment adjustment if the Secretary determines, subject to annual renewal, that requiring the EP to be a meaningful EHR user would result in a significant hardship. Such

exemptions are not granted once and applicable for a full five-year period. Under 495.102(d)(4)(iv)(C), an EP may receive a hardship exception if he or she has a primary specialty listed in PECOS as anesthesiology, radiology or pathology 6 months prior to the first day of the payment adjustments that would otherwise apply. The following five specialty codes correspond to those primary specialties in PECOS: Diagnostic Radiology (30), Nuclear Medicine (36), Interventional, Radiology (94), Anesthesiology (05), or Pathology (22).

Comment: A commenter expressed concern regarding the requirement that the hardship exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. Specifically, the commenter stated that a large percentage of these EPs practice in areas that do not have availability of CEHRT for demonstration of meaningful use. Because these providers lack control over availability of CEHRT for more than 50 percent of patient encounters, they cannot demonstrate meaningful use. The commenter anticipates these providers to continue practicing at multiple locations beyond the 5 years allowed for hardship exceptions. Some commenters suggested a hardship exemption should be available for EPs working in long term post-acute care (LTPAC) which should continue beyond the 5-year time limit; while other commenters questioned what if there is not sufficient broadband access in the region and 5 years may not be enough time for some remote areas to be “connected”. A commenter recommended simply eliminating the 5-year maximum for providers claiming this hardship exception.

Response: We are sympathetic to the challenges identified by the commenters and believe that barriers to achieving meaningful use should be minimized over time. As noted earlier, the 5-year limitation on hardship exceptions is a statutory requirement under section 1848(a)(7)(B) of the Act, and we do not have discretion to alter this requirement.

Comment: We received a suggestion from a commenter for an indication in the registration system that would identify the new EPs, which may be helpful to assist with program management. The commenter indicated for a large group practice, it is very difficult to determine if an EP is considered “new” by CMS standards and therefore may qualify for a hardship exception for newly practicing EPs. Some EPs have moonlighted during residency or fellowship and may be

considered eligible for this hardship exception.

Response: We appreciate the commenter’s suggestion about an indicator to identify a newly practicing EP in the registration system and will consider analysis to determine feasibility.

Comment: Commenters supported the existing hardship exception structure and categories for the Medicare payment adjustment in the EHR Incentive Programs. Some commenters requested a change the hardship exception application date for eligible hospitals to reflect the realignment to the calendar year.

Response: We appreciate the support expressed by commenters of our current process for hardship exceptions for eligible hospitals. We agree with the recommendation to modify the hardship exception application deadline for eligible hospitals to allow for adequate time between the close of the calendar year and the submission requirements for hardship applications. We will align the eligible hospital deadline with the EP deadline so that applications will be due on July 1 of the year preceding the payment adjustment year.

We are finalizing no changes to the types of hardship exceptions already available to EPs, eligible hospitals, and CAHs, nor do we finalize any new types of hardship exceptions. We are finalizing one procedural change to the hardship exception application deadline for eligible hospitals to July 1 of the year preceding the payment adjustment year to align the application period with EPs in light of the change to align hospitals with the calendar year for the EHR reporting period for a payment adjustment year and the changed attestation deadlines as finalized in section II.E.2.b and II.D of this final rule with comment period. This change is reflected in § 412.64(d)(4).

4. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

In the Stage 2 final rule (77 FR 54112 through 54113), we discussed an administrative appeals process for both Stages 1 and 2 of meaningful use. We believe this appeals process is primarily procedural and does not need to be specified in regulation. We developed guidance on the appeals process, which is available on our Web site at www.cms.gov/EHRIncentivePrograms. We proposed no changes to this process and intend to continue to specify the appeals process in guidance available on our Web site.

Comments: We received a number of comments with references to specific

instances of audits or appeals submitted. In addition, we received a wide range of recommendations for changes the auditors should make and for the requirements for the audit program. Finally, we received a number of comments expressing frustration with failed audits due to lack of response from the provider or the provider not receiving notification.

Response: We thank the commenters for sharing their experiences and insight with us. While we will not respond to each individual circumstance in this final rule with comment period, as this is not the appropriate vehicle to address these individual concerns, we note that providers may contact us directly and we will work with them to understand their audit or appeal status, review any determinations and provide information related to the programs. We also appreciate those who provided suggestions for additional guidance which might assist the auditors to make determinations on certain requirements for the program. We have reviewed this information and will update our guidance in response to recommendations received. Finally, we note that it is incumbent on providers to maintain the appropriate contact information in the system of record and regularly verify that their contact information is correct. It is this contact information provided by the EP, eligible hospital, or CAH which we use to notify the provider of any status update or audit request for the EHR Incentive Programs. Once notification has been sent, it is also this contact information which is used by the auditors to communicate with the provider on status, documentation requests, and any other necessary items in order to expedite the audit process and ensure the use of verified and authorized contact information for the EP, eligible hospital or CAH.

We are finalizing our proposal to maintain this policy as previously adopted.

F. Medicare Advantage Organization Incentive Payments

We did not propose any changes to the existing policies and regulations for MA organizations. Our existing policies and regulations include provisions concerning the EHR incentive payments to qualifying MA organizations and the payment adjustments for 2015 and subsequent MA payment adjustment years. (For more information on MA organization incentive payments, we refer readers to the final rules for Stages 1 and 2 (75 FR 44468 through 44482 and 77 FR 54113 through 54119).)

Comment: A commenter requested clarification that CMS is not changing the quality reporting requirements for MA organizations in this proposed rule so that MA providers may still meet the quality reporting requirements by way of their Healthcare Effectiveness Data and Information Set (HEDIS) submission. Another commenter requested that hardship exceptions be granted to MA providers under the same provisions available for non-MA providers.

Response: We are confirming that we will continue to allow MA organizations to report HEDIS measures in lieu of CQMs for purposes of meaningful use for qualifying MA-EPs and MA-affiliated eligible hospitals.

We did not propose any changes to the hardship exemption policy for MA providers in the proposed regulation. Therefore, the comment is outside the scope of the proposed rule and is not addressed in this final rule with comment period.

G. The Medicaid EHR Incentive Program

1. State Flexibility for Meaningful Use

Consistent with our approach under both Stage 1 and 2, for Stage 3 we proposed to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3 by adding a new provision at § 495.316(d)(2)(iii) subject to the same conditions and standards as the Stage 2 flexibility policy. We proposed that under Stage 3 (80 FR 16779), state flexibility would apply only with respect to the public health and clinical data registry reporting objective. We proposed that states could continue to specify the means of transmission of data and otherwise change the public health agency reporting objective as long as the state does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition proposed rule.

Similarly, in the preamble to the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20349), we proposed to continue to offer states flexibility for the public health reporting objective as modified under Stage 2 for 2015 through 2017. We would continue the policy stated in the Stage 2 final rule (77 FR 53979) to allow states to specify the means of transmission of the data or otherwise change the public health measure as long as it does not require EHR functionality that supersedes that which is included in the certification requirements specified under the 2014 Edition certification criteria.

Comment: Commenters requested clarification on the state flexibility that

would be permitted. One commenter requested clarification on whether immunization registries would be included, whether states could continue to specify transport options, and whether states could decide not to declare readiness to accept submissions to clinical data registries for meaningful use purposes.

Response: We note that the state flexibility to propose a revised definition of meaningful use with respect to particular public health measures continues as allowed in Stage 1 and Stage 2 at § 495.316(d)(2) and § 495.332(f)(2). We note that the final rule has altered the structure of meaningful use under Stage 2 with respect to the public health and clinical data registry reporting measures, such that there is a single objective with a list of measures that providers may choose from. However, we would still permit states to exercise flexibility with respect to each of the Stage 2 items listed at § 495.316(d)(2)(ii) that still apply in 2015 through 2017 under this final rule. We will also take the following considerations into account when, as part of our review and approval of the state's Medicaid HIT plan, we review state requests for flexibility with respect to the public health reporting objective (Objective 8) for Stage 3 (see section II.B.2.b.(viii). of this final rule with comment period. We want to balance states' flexibility to customize the public health and clinical data registry requirements for meaningful use against ensuring providers have options to submit to registries that are most relevant to their practices. Therefore, we expect that for Stage 3 we would be more likely to approve requests under which a state would require an EPs, eligible hospitals and CAHs to submit to a specific registry meeting the specification of measures 1 through 4 or 6 rather than establishing specific requirements for measure 5.

The flexibility to specify transmission standards remains unchanged from the Stage 2 Rule. In the Stage 2 final rule (77 FR 53979), we explained that a state could not require a different standard than the one included in 2014 ONC EHR certification criteria, but in cases where the 2014 ONC EHR certification criteria are silent, such as the means of transmission for a given public health objective, the state may propose changes to public health measures. We maintain this distinction for Stage 3 in relation to the 2015 ONC certification criteria for health IT.

Comment: Most commenters supported the new provision to provide states with flexibility regarding the Stage 3 public health and clinical data

registry reporting objective. One commenter questioned whether a state could opt to not declare readiness to accept clinical data registries for meaningful use purposes, expressing concern that providers may prioritize reporting to federal clinical data registries over the public health reporting objectives. Another commenter expressed concern that this flexibility would lead to differing objectives and measures among the states instead of a consistent, standard approach.

Response: We proposed to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3, but subject to the same considerations discussed previously in Stage 2 (77 FR 53979). For Stage 3 of meaningful use, we would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective as long as they do not require functionality greater than what is required for Stage 3 and included in the 2015 Edition final rule. States may change the definition of meaningful use with respect to the public health registry and clinical data registry reporting objective as discussed in our earlier response. While this policy may lead to variations in the definition of meaningful use with respect to this objective among the states, we believe that it is important to allow states to better shape their public health policies and encourage providers to submit data to particular public health registries.

States generally do not have discretion to categorically deny providers from using clinical data registries to meet the public health and clinical data registry reporting objective, so long as the clinical data repositories fall within federal rules and guidance. To address concerns that providers may be discouraged from attesting to public health registries, we reiterate that states can submit for CMS approval revisions to their SMHPs that would require that providers meet certain measures.

We are finalizing the Stage 3 state flexibility provision generally as proposed, with only a minor change to update a cross-reference to the public health and clinical data registry objective.

2. EHR Reporting Period and EHR Reporting Period for a Payment Adjustment Year for First Time Meaningful EHR Users in Medicaid

In the Stage 3 proposed rule (80 FR 16779), we proposed several amendments to the definitions of “EHR Reporting Period” and “EHR reporting

period for a payment adjustment year” in § 495.4 that would apply to providers attesting in the Medicaid EHR Incentive Program. While many of the proposed amendments would apply to providers attesting in either the Medicare or Medicaid EHR Incentive Program, we also proposed a limited exception for new meaningful EHR users in the Medicaid program beginning in 2017.

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20353 and 20354), we proposed that all providers (EPs, eligible hospitals, and CAHs) would be required to complete an EHR reporting period within January 1 and December 31 of the calendar year in order to fulfill the requirements of the EHR Incentive Programs beginning in calendar year 2015 (except for eligible hospitals and CAHs in 2015, which may begin an EHR reporting period as early as October 1, 2014 and must end by December 31, 2015). We also proposed that for an EHR reporting period in 2015, eligible professionals may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015. These proposed amendments and the final policies adopted are discussed in sections II.B.1.b.(3).(i) and (ii) of this final rule with comment period.

In the Stage 3 proposed rule (80 FR 16739), we proposed that beginning in 2017 and for all EPs, eligible hospitals, and CAHs, the EHR reporting period would be one full calendar year. This proposed amendment is discussed in section II.B.1.b.(3).(iii) of this final rule with comment period, and is finalized with a modification to begin for all providers in 2018 and multiple modifications to the EHR reporting period in 2017. For EPs, eligible hospitals, and CAHs that choose to meet Stage 3 in 2017, the EHR reporting period is any continuous 90-day period within CY 2017. For new participants, the EHR reporting period is any continuous 90-day reporting period within CY 2017. These modifications regarding providers attesting to Stage 3 of meaningful use in 2017 applies to providers attesting to the Medicaid EHR Incentive Program as well.

In the Stage 3 proposed rule (80 FR 16739), we also proposed a limited exception for Medicaid providers demonstrating meaningful use for the first time in 2017 and subsequent years. For that exception, we proposed to maintain the 90-day EHR reporting period for a provider’s first payment year based on meaningful use for EPs

and eligible hospitals participating in the Medicaid EHR Incentive Program. We proposed that this exception would apply both for purposes of receiving an incentive payment in the Medicaid program and for purposes of avoiding the payment adjustment under the Medicare program for the payment adjustment year that is two years after the calendar year in which the provider first demonstrates meaningful use for an EHR reporting period. As the last year that an eligible professional can begin participation in the Medicaid EHR Incentive Program is 2016, this limited exception would apply only to providers who received an incentive payment for adopt, implement, or upgrade of CEHRT in 2011 through 2016, but did not receive an incentive payment for demonstration of meaningful use until 2017 or after. In this section, we address comments received on this limited exception for new meaningful EHR users in the Medicaid program.

Comment: Several commenters supported the proposal to allow Medicaid providers to have a 90-day EHR reporting period for their first year of demonstrating meaningful use under the Medicaid EHR Incentive Program.

Response: We refer readers to sections II.B.1.b.(3) and II.E.2. of this final rule with comment period with comment period for a discussion of our final policies for Medicaid providers for the EHR reporting period and the EHR reporting period for a payment adjustment year.

We believe that these changes will allow flexibility for providers who have not demonstrated meaningful use in a previous year and will encourage providers to participate in the program.

Comment: Some commenters opposed the proposed 90-day EHR reporting period for certain Medicaid providers because they believed it would cause confusion as it conflicts with the proposed Medicare policy. In addition, these commenters were concerned that providers attesting to the 90-day EHR reporting period for Medicaid would still be subject to the Medicare payment adjustment.

Response: We recognize the possibility of provider confusion regarding EHR reporting periods between the Medicare and Medicaid EHR Incentive Programs under the final rule, but we believe that there are benefits that outweigh this potential concern. A 90-day EHR reporting period would allow Medicaid providers additional time and flexibility within their first year of demonstrating meaningful use to implement certified EHR technology and otherwise integrate

the meaningful use objectives into their practices. We believe that this will encourage participation in the program and move a greater number of providers towards meaningful use. It also would reduce the burden on states to implement significant policy and system changes in preparation for Stage 3, as the 90-day period for the first year of meaningful use is consistent with our previous policies and meaningful use timelines. With regard to the question raised by commenters if providers attesting to the 90-day EHR reporting period for Medicaid may still be subject to the Medicare payment adjustment, we refer to our discussion of the EHR reporting period for the payment adjustment year in section II.E.2. of this final rule with comment period.

Comment: Some commenters requested that CMS allow states to give providers the option to attest to “at least 90 days or 3 calendar months,” rather than 90 days within the calendar year, because it is more convenient for providers to run reports out of their CEHRT by month.

Response: We believe that it is important to maintain a consistent EHR reporting period for providers in their first year of meaningful use and changing the EHR period at this point also risks provider confusion. Allowing 3 calendar months would open the possibility of a reporting period that is shorter than 90 days, and we believe that 90 days is already a short period as compared to the entire year. Furthermore, a 90-day period need not be tied to the beginning or end of a month and permits flexibility for providers.

Comment: A commenter requested that CMS provide outreach and education to assure understanding of the 90-day EHR reporting period for Medicaid providers demonstrating meaningful use for the first time.

Response: We will provide outreach and education around this policy. Because the exception for new meaningful EHR users in the Medicaid program who had successfully attested to AIU prior to 2016 to allow a 90-day EHR reporting period in 2018 and subsequent years is consistent with existing policy with respect to Medicaid provider EHR reporting periods, we do not anticipate significant additional confusion.

3. Reporting Requirements

a. State Reporting on Program Activities

In the Stage 3 proposed rule (80 FR 16779), we also proposed to amend § 495.316(c), as well as add a new paragraph § 495.316(f), to formalize the

process of how states report to us annually on the providers that have attested to adopt, implement, or upgrade (AIU), or that have attested to meaningful use. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS, which would include a new annual reporting deadline. We proposed to require states to submit annual reports to CMS within 45 days of the end of the second quarter of each federal fiscal year.

We proposed to regularize the timing of the annual reporting process described in § 495.316 to ensure more timely annual reports and allow for clearer communication to states on when the reports should be submitted to CMS. In addition, CMS and states would be able to more effectively track the progress of states’ incentive program implementation and oversight as well as provider progress in achieving meaningful use. Predictable deadlines for annual reporting would permit CMS and the states to more quickly compare and assess overall program impact each year.

In the Stage 3 proposed rule (80 FR 16779), we also noted our intent to consider changes to the data that the annual reporting requirements outlined in § 495.316(d) require states to include in their annual reports. Specifically, we explained we were considering whether to remove the requirement that states report information about practice location for providers that qualify for incentive payments on the basis of having adopted, implemented, or upgraded CEHRT or on the basis of demonstrating they are meaningful users of CEHRT. We stated our belief that this data is useful to both CMS and the states for program implementation purposes, but that the benefits of including it in state reports might be outweighed by the burdens to states of reporting it and requested more information on state burdens and costs associated with complying with this requirement. We solicited comments both on the burdens associated with the requirement to report practice location information for providers that receive incentive payments through the Medicaid EHR Incentive Program, and on the benefits of including this information in state reports.

We proposed to amend § 495.352 to formalize the process of how states submit quarterly progress reports on implementation and oversight activities and to specify the elements that should be included in the quarterly reports. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS. We

proposed that states would report on the following activities: State system implementation dates; provider outreach; auditing; state-specific SMHP tasks; state staffing levels and changes; the number and type of providers that qualified for an incentive payment on the basis of demonstrating that they are meaningful EHR users of CEHRT and the amounts of incentive payments; and the number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented, or upgraded CEHRT and the amounts of incentive payments.

We proposed these changes to the quarterly reporting process described in § 495.352 so that CMS and states can better track state implementation and oversight activity progress in a way that would permit CMS and the states to compare overall programmatic and provider progress. We also expect that streamlined and enhanced quarterly progress reporting would lead to an improvement in overall data quality that would help inform future meaningful use activity across states.

Finally, we proposed to include a deadline for states’ quarterly reporting under the proposed amendments to § 495.352, and requested public comment on a deadline of 30 days after the end of each federal fiscal year quarter.

Comment: Commenters supported formalizing the process of how states report annually on the providers that have attested to AIU, or that have attested to meaningful use, but requested to submit annual reports within 60 days of the end of the second quarter of each federal fiscal year rather than the 45 days proposed in the rule. A commenter stated that this will alleviate systems and programming changes typically faced by states at the end of the calendar year, while another commenter expressed that states would need more time to produce current program year data to be included in the annual report.

Response: We agree with the commenter’s statements regarding the implications of year-end program changes and the need for additional time to produce related data. Therefore, we are finalizing these provisions to require that annual reports be submitted to CMS within 60 days of the end of the second quarter of each federal fiscal year rather than 45 days, as was proposed. States should have ample time to prepare to submit the annual reports to CMS, and we are not adding additional data elements for states to report; therefore, the first report under this amendment will be due within 60 days of the end of the second quarter of

the federal fiscal year in which the final rule takes effect.

Comment: Commenters supported our proposal to remove practice location from the annual report. A commenter noted that their state already reports practice location, but does not find this data point to be beneficial and is in favor of removing this requirement. Another commenter finds this requirement to be burdensome because it requires manual review of attestations in order to identify accurate data on practice locations, and fears this will lead to inaccurate data.

Response: We appreciate the commenters' feedback on this topic. While we believe that there is a benefit to having states report this information in the annual reports, we believe that this benefit is outweighed by the burden of states having to collect and report this information on providers. Moreover, there is also a risk that inaccurate practice location data may be reported due to manual data collection processes. We believe that we can effectively oversee the program without states reporting this particular information. Therefore, we intend to remove the requirement at § 495.316(d)(1)(i) and (iii) that states report information about practice location for providers that qualify for incentive payments on the basis of having adopted, implemented, or upgraded CEHRT or on the basis of demonstrating they are meaningful users of CEHRT. We encourage states to collect and use practice location information, as it could prove useful and may differ from the business address information that is used for program administration purposes.

Comment: Commenters supported the proposed requirement for states to submit quarterly progress reports to CMS within 30 days after the end of each federal fiscal year quarter and do not anticipate that this requirement would create any burden.

Response: Based on the positive feedback we are finalizing the proposal with a modification to require the deadline of 30 days after the end of each federal fiscal year quarter that was discussed in the proposed rule. In order to give states sufficient time to prepare to submit the quarterly reports, the first report under the amendments to § 495.352 will be due in the second quarter following the one in which the final rule takes effect.

Comment: A commenter recommended that all public health measures collected or tracked through the state reporting activities be reported to the public health agency.

Response: We support the notion of sharing public health measures

collected through state reporting activities with the designated public health agency, but also recognize that the mechanism and interface between the reporting organization and the public health agency must be live, operational, and capable of interfacing with all parties involved. Additionally, our state reporting provisions are meant to cover reporting from state Medicaid agencies to CMS. We decline to add a requirement that state Medicaid agencies report this data to other entities, including public health agencies.

b. State Reporting on Meaningful EHR Users

In the Stage 3 proposed rule at (80 FR 16780), we noted that CMS must have accurate and timely data from states regarding both EPs and eligible hospitals that have successfully demonstrated meaningful use for each payment year to ensure that meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment for the applicable payment adjustment year. Accordingly, we proposed to add new paragraphs (g) and (h) to § 495.316 to require that states submit reports on a quarterly basis that identify certain providers that attested to meaningful use through the Medicaid EHR Incentive Program for each payment year. Under this proposal, states would submit quarterly reports, in the manner prescribed by CMS, for Medicaid EPs and eligible hospitals that successfully attest to meaningful use for each payment year.

We proposed that states would report quarterly information on each provider that successfully attests to meaningful use, regardless of whether the provider has been paid yet. The report would be required to specify the Medicaid state and payment year. For each EP or eligible hospital listed in the report, the state would also specify the payment year number, the NPI for EPs and the CCN for eligible hospitals, the attestation submission date, the state qualification (as either meaningful use or blank), and the state qualification date (the beginning date of the reporting period in which successful meaningful use attestation was achieved by the EP or eligible hospital). The EP's or eligible hospital's "payment year number" refers to the number of years that the provider has been paid in the EHR Incentive Program; so, for example, this would be "2" for the 2014 payment year if the provider received payments for 2013 and 2014. States would have this data, even for providers that have previously received an incentive

payment through the Medicare EHR Incentive Program. If the state is reporting a disqualification, then the state would leave the state qualification field blank. If applicable, in the cases of EPs or eligible hospitals previously identified as meaningful EHR users, the state would be required to specify the state disqualification and state disqualification date (that is, the beginning date of the EHR reporting period during which an EP or eligible hospital was found not to meet the definition of a meaningful EHR user).

We also proposed that states would submit this information beginning with payment year 2013 data. The reports would cover back to the 2013 payment year because that would be the EHR reporting period for the 2015 Medicare payment adjustment year under § 495.4. Providers that successfully attested to meaningful use for 2013 would be exempt from the Medicare payment adjustment in 2015.

We also proposed that states would not be required to report on those EPs who are eligible for the Medicaid EHR Incentive Program on the basis of being a nurse practitioner, certified nurse-midwife, or physician assistant.

Comment: Most comments favored and expressed no concern with the associated requirements, nor anticipated burden. A commenter shared that he or she found the state reporting on Meaningful EHR Users to be time consuming and suggested that we use the National Level Repository (NLR) transactions to determine meaningful users and remove this burden from the states. In this commenter's view, the payment adjustment is a Medicare function; therefore states should be removed from the process. Another commenter requested that we further clarify who is exempt from the state reporting.

Response: We intend to finalize these provisions as proposed for the reasons provided in the preamble to the Stage 3 proposed rule. As outlined in the Stage 3 proposed rule (80 FR 16780), we must have accurate and timely data from states regarding both EPs and eligible hospitals to ensure that meaningful users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment for the applicable payment adjustment year. This additional reporting is necessary because the electronic data currently contained in the NLR are insufficient to determine which Medicaid providers should be exempted from the Medicare payment adjustments in an accurate and timely manner. Regarding the exemption with respect to reports on certain providers, we are not

requiring states to report on nurse practitioners, certified nurse-midwives, or physician assistants because these provider types are not subject to the Medicare payment adjustments. The first report under this requirement will be due in the quarter following the one in which the rule takes effect.

4. Clinical Quality Measurement for the Medicaid Program

In the Stage 3 proposed rule (80 FR 16780), we noted that states are responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to allow reporting through attestation. If a state does require electronic reporting, the state is responsible for sharing the details on the process with its provider community. States that wish to establish the method and requirements for electronically reporting would continue to be required to do so through the SMHP submission, subject to our prior approval.

To further our goals of alignment and avoiding duplicative reporting across quality reporting programs, we would recommend that states include a narrative in their SMHP for CY 2017 describing how their proposed meaningful use CQM data submission strategy aligns with their State Medicaid Quality Strategy and report which CEHRT requirements they mandate for eCQM reporting.

For more information on requirements around the State Medicaid Quality Strategy, see <http://medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-13-007.pdf>.

Comment: A commenter supported the proposal to continue allowing states to be responsible for determining how providers will report CQMs because not all states are at the same readiness level to accept eCQMs, and states must implement system changes to accommodate policy change.

Response: We appreciate this comment, and we are finalizing this policy as proposed.

Comment: A number of commenters provided feedback regarding Medicaid quality improvement initiatives and recommendations on how to best conduct outreach and engagement to providers and patients in various clinical settings. Commenters also recommended ways to publicize EP accomplishments in providing essential health services to patients benefiting from the Medicaid EHR Incentive Program. In addition, commenters encouraged CMS to continue its conversations with state Medicaid agencies and health groups in an effort to explore the issues faced by eligible

providers attempting to meaningfully use EHR in areas with large numbers of uninsured populations. They also recommended that CMS continue to encourage state Medicaid programs to collaborate with public health agencies, and to assist in reducing barriers to the use of Federal funding to build public health information infrastructure. A commenter recommended changes to the Medicaid patient-volume rules.

Response: We will consider these recommendations as we develop future planning for long-term delivery system reform and related policies. We note that some of these comments were outside of the scope of the proposed rules.

III. Collection of Information Requirements

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

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

The following is a discussion of the requirements contained in the proposed regulations that we believed were subject to PRA and collection of information requirements (ICRs) as a result of this final rule with comment period. This analysis finalizes our projections which were proposed in the March 30, 2015 **Federal Register** (80 FR 16781 through 16787) and the April 15, 2015 **Federal Register** (80 FR 20381 through 20386). The projected numbers of EPs, eligible hospitals, CAHs, MA organizations, MA EPs, and MA-affiliated hospitals were based on the numbers used in the impact analysis assumptions, as well as estimated federal costs and savings in the sections of the proposed rules. The actual burden would remain constant for all of Stage 3 as EPs, eligible hospitals, and CAHs would only need to attest that they have successfully demonstrated meaningful use in 2017 and annually thereafter. The

actual burden would remain constant for 2015 through 2017 as EPs, eligible hospitals, and CAHs would only need to attest that they have successfully demonstrated meaningful use in 2015 through 2017. The only variable from year to year will be the number of respondents, as noted in the impact analysis assumptions.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.24)

This final rule with comment period specifies applicable criteria for demonstrating meaningful use of CEHRT for EHR reporting periods in 2015 through 2017 and for Stage 3 in 2017 and subsequent years. The applicable criteria for demonstrating meaningful use for an EHR reporting period in 2015 through 2017 are based on modifications to the criteria previously set out in Stage 1 and 2 of the EHR Incentive Programs. These changes in the overall burden for providers reporting in 2015 through 2017 are discussed in further detail in the ICR analysis for 2015 through 2017 outlined in section III.B of this final rule with comment period. The ICRs in this section (that is, section III.A. of this final rule with comment period) reflect the provider burden associated with complying with and reporting of Stage 3 requirements beginning in 2017 and each subsequent year.

In § 495.24 (redesignated from § 495.7) we proposed that to successfully demonstrate meaningful use of CEHRT for Stage 3, an EP, eligible hospital, or CAH (collectively referred to as “provider” in this section) must attest, through a secure mechanism in a specified manner, to the following during the EHR reporting period:

- The provider used CEHRT and specified the technology was used.
- The provider satisfied each of the applicable objectives and associated measures in § 495.26.

In § 495.40 (redesignated from § 495.8), we stipulated that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimated that the CEHRT adopted by the provider captures many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We noted that we also expect that the provider would enable the functionality required to complete

the objectives and associated measures that require the provider to attest that they have done so.

We proposed that there would be five objectives and ten measures that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest they have met five objectives and ten measures that would require numerators and denominators. For objectives and associated measures requiring a numerator and denominator in the proposed rule, we limited our estimates to actions taken in the presence of certified EHR technology. We did not anticipate a provider would maintain two recordkeeping systems when CEHRT is present. Therefore, we assumed that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expected it would take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated. The security risk assessment and its associated measure would not require a numerator and denominator and we would expect it would take an individual provider or designee approximately 6 hours to complete. The clinical decision support and active engagement with a public health agency measures would take an eligible professional, eligible hospital or critical access hospital 1 minute each to report each CDS intervention or registry.

We proposed that EPs would be required to report on a total of 8 objectives and 16 associated measures. For the purpose of the proposed collection of information, we assumed that all eligible providers would comply with the requirements of meaningful use Stage 3. We proposed that eligible hospitals and CAHs would be required to report on a total of 8 objectives and 17 associated measures. We estimated the total annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be \$2,135,204 (4,900 eligible hospitals and CAHs × 6 hours 52 minutes × \$63.46²¹). We estimated

the total annual cost burden for all EPs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be \$385,834,395 (609,100 EPs × 6 hours 52 minutes × \$92.25 (mean hourly rate for physicians based on May 2013 BLS) data).

Comment: One commenter noted that the time to attest is likely accurate; however, they stated that the estimate does not reflect the dollars and resources spent on software upgrades, implementation costs, continuous auditing, and the gathering of data for calculation.

Response: We appreciate the public comments on this burden analysis. However, this analysis specifically reflects the amount of time we estimate providers will take to prepare and report their meaningful use data through the Medicare and Medicaid EHR Incentive Programs Registration and Attestation System. We cannot account for other costs related to participation in these programs or for variation in how an individual provider may collect, calculate or document actions related to their unique business practices and systems workflows.

After consideration of the public comments received, we are finalizing these burden estimates as proposed but have updated them to reflect policy changes implemented through this final rule with comment period.

In this final rule with comment period, there were five objectives that will require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs will have to attest that they have met five objectives that require numerators and denominators. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider will maintain two recordkeeping systems when CEHRT is present. Therefore, we assume that all patient records that will be counted in the denominator will be kept using certified EHR technology. We expect it will take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated, as well as each CQM for

providers attesting in their first year of the program.

Additionally, providers will be required to report they have completed objectives and associated measures that require a “yes” or “no” response during attestation. For EPs, there are three objectives that require a “yes” or “no” response during attestation. As discussed previously, the associated measures are that EPs are required to conduct a security risk analysis, report to three registries to fulfill the public health objective, and must implement at least five clinical decision support interventions. For eligible hospitals and CAHs, there are three objectives that require a “yes” or “no” response during attestation. The associated measures for eligible hospitals and CAHs require the provider to conduct a security risk analysis, report to four registries to fulfill the public health objective and must implement at least five clinical decision support interventions. We estimate each of these measures would take 1 minute to report.

Providers will also be required to attest that they are protecting electronic health information. We estimate completion of the analysis required to meet successfully the associated measure for this objective will take approximately 6 hours, which is identical to our estimate for the Stage 1 and Stage 2 requirements. This burden estimate assumes that covered entities are already conducting and reviewing these risk analyses under current HIPAA regulations. Therefore, we do not account for the additional burden associated with the conduct or review of such analyses.

Table 21 lists the Stage 3 objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the objectives and associated measures will take an EP 6 hours 52 minutes to complete, and will take an eligible hospital or CAH 6 hours 52 minutes to complete.

We believe that EPs, eligible hospitals, and CAHs have virtually identical burdens. Eligible hospitals and CAHs are required to report to one additional registry than EPs are required to report. Consequently, we did not prepare lowest and highest burdens. Rather, we computed a burden for EPs and a burden for eligible hospitals and CAHs.

²¹ Mean hourly rate for lawyers based on May 2013 Business and Labor Statistics (BLS) data.

TABLE 21—BURDEN ESTIMATES STAGE 3—§ 495.24

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.	6 hours	6 hours.
Generate and transmit permissible prescriptions electronically (eRx).	Generate and transmit permissible discharge prescriptions electronically (eRx).	1. EP Measure: More than 60% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. 2. Eligible Hospital/CAH Measure: More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes	10 minutes.
Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Measure 1. The EP, eligible hospital and CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	1 minute	1 minute.
Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Measure 1. More than 60 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE. Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE. Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	10 minutes	10 minutes.

TABLE 21—BURDEN ESTIMATES STAGE 3—§ 495.24—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
<p>The EP provides patients or their authorized representatives electronic access to their health information and patient-specific education.</p>	<p>The eligible hospital or CAH provides patients or their authorized representatives electronic access to their health information and patient-specific education.</p>	<p>Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <ul style="list-style-type: none"> (1) The patient (or the patient-authorized representative) is provided access to view online, download, and transmit his or her health information; and (2) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT. <p>Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p>	<p>10 minutes</p>	<p>10 minutes.</p>
<p>Use CEHRT to engage with patients or their authorized representatives about the patient's care.</p>	<p>Use CEHRT to engage with patients or their authorized representatives about the patient's care.</p>	<p>Measure 1: During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the EHR made accessible by the provider and either:</p> <ul style="list-style-type: none"> (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2). <p>Measure 2: For more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).</p>	<p>10 minutes</p>	<p>10 minutes.</p>

TABLE 21—BURDEN ESTIMATES STAGE 3—§ 495.24—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
<p>The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.</p>	<p>The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.</p>	<p>Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH (POS 21 or 23) during the EHR reporting period.</p> <p>Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.</p> <p>Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's record an electronic summary of care document from a source other than the provider's EHR system.</p> <p>Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets: <i>Medication.</i> Review of the patient's medication, including the name, dosage, frequency, and route of each medication. <i>Medication allergy.</i> Review of the patient's known medication allergies. <i>Current Problem list.</i> Review of the patient's current and active diagnoses.</p>	<p>10 minutes</p>	<p>10 minutes.</p>
<p>The EP is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.</p>	<p>.....</p>	<p>Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</p> <p>Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting (urgent care ambulatory for EP, emergency or urgent care department for eligible hospitals and CAHs).</p>	<p>1 minute</p>	<p>1 minute.</p>

TABLE 21—BURDEN ESTIMATES STAGE 3—§ 495.24—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	<p>The eligible hospital or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.</p>	<p>Measure 3—Electronic Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p> <p>Measure 4—Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.</p> <p>Measure 5—Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</p> <p>EPs must meet 2 measures and may choose to report to more than one public health registry or clinical data registry to meet the objective.</p> <p>Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</p> <p>Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting (urgent care ambulatory for EP, emergency or urgent care department for eligible hospitals and CAHs).</p> <p>Measure 3—Electronic Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p> <p>Measure 4—Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.</p> <p>Measure 5—Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</p> <p>Measure 6—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit ELR results.</p>	<p>1 minute</p>	<p>1 minute.</p>

TABLE 21—BURDEN ESTIMATES STAGE 3—§ 495.24—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Criteria Burden	Eligible Hospitals and CAHs must meet 4 measures and may choose to report to more than one public health registry and/or clinical data registry to meet the objective.	6 hours 52 minutes	6 hours 52 minutes
Time to Attest and Report Clinical Quality Measures. Total—Criteria Burden.	6 hours 52 minutes	6 hours 52 minutes

In this final rule with comment period, we estimate that it will take no longer than 6 hours and 52 minutes for an EP to report on each of the applicable objectives and associated measures. The total burden hours for an EP to attest to the criteria previously specified will be 6 hours 52 minutes. We estimate that there could be approximately 609,100 non-hospital-based Medicare and Medicaid EPs in 2017.

We estimate the burden for the approximately 13,635 MA EPs in the MAO burden section. We estimate the total burden associated with these requirements for an EP will be 6 hours 52 minutes. The total estimate annual cost burden for all EPs to attest to EHR technology and meaningful use objectives will be \$385,834,395 (506,400 × 6 hours 52 minutes × \$92.25 (mean hourly rate for physicians based on May 2013 BLS data)).

Similarly, eligible hospitals and CAHs will attest that they have met the core meaningful use objectives and associated measures, and will electronically submit the clinical quality measures. We estimate that it will take no longer, than 6 hours and 52 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specified the EHR technology used, and satisfied each of the applicable objectives and associated measures. We estimate that there are about 4,900 eligible hospitals and CAHs (3,397 acute care hospitals, 1,395 CAHs, 97 children’s hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria in FY 2017. We estimate the total burden associated with these requirements for an eligible hospital and CAH would be 6 hours 52 minutes. The total estimated annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use core set and menu set criteria, and electronically submit the clinical quality measures will be \$2,135,204 (4,908 eligible hospitals and

CAHs × \$63.46 (6 hours 52 minutes × \$63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)).

B. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.20 through § 495.60)

In § 495.40 we proposed that to successfully demonstrate meaningful use of CEHRT for meaningful use in 2015 through 2017, an EP, eligible hospital, or CAH (collectively referred to as “provider” in this section) must attest, through a secure mechanism in a specified manner, to the following during the EHR reporting period: (1) The provider used CEHRT and specified the technology was used; and (2) the provider satisfied each of the applicable objectives and associated measures in § 495.22. In § 495.40, we stipulated that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimated that the CEHRT adopted by the provider captures many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We also expected that the provider would enable the functionality required to complete the objectives and associated measures for which they are required to attest.

We proposed that EPs would be required to report on a total of ten objectives and associated measures and eligible hospitals and CAHs would report on a total of nine objectives and associated measures. There are six objectives that will require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs will have to attest that they have met six objectives that require numerators and denominators. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR

technology. We do not anticipate a provider would maintain two recordkeeping systems when CEHRT is present. Therefore, we assumed that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it will take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated, as well as approximately 1 hour 30 minutes to attest to CQM requirements.

Additionally, providers would be required to report they have completed objectives and associated measures that require a “yes” or “no” response during attestation. For EPs, there are three objectives that would require a “yes” or “no” response during attestation. For eligible hospitals and CAHs, there are 2 objectives and that would require a “yes” or “no” response during attestation. We expect that it would take a provider or their designee 1 minute to attest to each objective that requires a “yes” or “no” response.

Providers would also be required to attest that they are protecting ePHI. We estimate completion of the analysis required to meet successfully the associated measure for this objective would take approximately 6 hours, which is identical to our estimate for the Stage 1 and Stage 2 requirements. This burden estimate assumes that covered entities are already conducting and reviewing these risk analyses under current HIPAA regulations. Therefore, we have not accounted for the additional burden associated with the conduct or review of such analyses.

We estimate the objectives and associated measures would take an EP 6 hours 49 minutes to complete, and would take an eligible hospital or CAH 6 hours 48 minutes to complete.

Comment: Some stated that CMS should account for the amount of time

required to prepare for attestation. They also stated that CMS should more carefully consider the multiple factors that contribute to the burden of physician reporting.

Response: We appreciate the public comments on this burden analysis. However, this analysis specifically reflects the amount of time we estimate providers will take to prepare and report their meaningful use data through the Medicare and Medicaid EHR Incentive

Programs Registration and Attestation System.

After consideration of the public comments received, we are finalizing these burden estimates as proposed but have updated them to reflect policy changes implemented through this final rule with comment period. In this final rule with comment period, there are 10 objectives for EPs and 9 objectives for eligible hospitals and CAHs.

Table 22 lists those objectives and associated measures for EPs and eligible

hospitals and CAHs. EPs, eligible hospitals, and CAHs have nearly identical reporting burdens. Eligible hospitals and CAHs are required to report to one additional registry than EPs are required to report. However, EPs have an additional objective, Secure Electronic Messaging, which requires a “yes” or “no” response. Consequently, we have not prepared lowest and highest burdens. Rather, we have computed a burden for EPs and a burden for eligible hospitals and CAHs.

TABLE 22—BURDEN ESTIMATES—§ 495.22

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (Hospitals)
Objectives and Measures				
Protect ePHI created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Protect ePHI created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider’s risk management process.	6 hours	6 hours.
Use clinical decision support to improve performance on high-priority health conditions.	Use clinical decision support to improve performance on high-priority health conditions.	1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH’s scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. 2. The EP, eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	1 minute	1 minute.
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.	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.	More than 60% of medication, 30% of laboratory, and 30% of radiology orders created by the EP or authorized providers of the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	10 minutes	10 minutes.
Generate and transmit permissible prescriptions electronically (eRx).	More than 50% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes	
	Generate and transmit permissible discharge prescriptions electronically (eRx).	More than 10% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes.

TABLE 22—BURDEN ESTIMATES—§ 495.22—Continued

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (Hospitals)
The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	1. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.	10 minutes	10 minutes.
Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient. Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.	Patient-specific education resources identified by CEHRT are provided to patients for more than 10% of all unique patients with office visits seen by the EP during the EHR reporting period. More than 10% of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient-specific education resources identified by CEHRT.	10 minutes.	10 minutes.
The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The eligible hospital 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.	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	10 minutes	10 minutes.
Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.	1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely online access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information. 2. For 2015 and 2016: At least 1 patient seen by the EP during the EHR reporting period (or his or her authorized representative) views, downloads or transmits his or her health information to a third party during the EHR reporting period. For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads or transmits their health information to a third party during the EHR reporting period.	10 minutes.	

TABLE 22—BURDEN ESTIMATES—§ 495.22—Continued

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (Hospitals)
<p>Use secure electronic messaging to communicate with patients on relevant health information.</p>	<p>Provide patients the ability to view online, download, and transmit their health information within 36 hours of hospital discharge.</p>	<p>1. More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH are provided timely access to view online, download and transmit their health information to a third party their health information.</p> <p>2. For 2015 and 2016: At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads, or transmits to a third party his or her health information during the EHR reporting period.</p> <p>For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period.</p>	<p>.....</p>	<p>10 minutes.</p>
	<p>.....</p>	<p>For 2015: For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled. For 2016: For at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period. For 2017: For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	<p>10 minutes.</p>	

TABLE 22—BURDEN ESTIMATES—§ 495.22—Continued

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (Hospitals)
The EP is in active engagement with a public health agency to submit electronic public health data from CEHRT except where prohibited and in accordance with applicable law and practice.	Stage 1 EPs in 2015 must meet at least 1 measure in 2015, Stage 2 EPs must meet at least 2 measures in 2015, and all EPs must meet at least 2 measures in 2016 and 2017. <i>Measure 1—Immunization Registry Reporting:</i> The EP is in active engagement with a public health agency to submit immunization data. <i>Measure 2—Syndromic Surveillance Reporting:</i> The EP is in active engagement with a public health agency to submit syndromic surveillance data. <i>Measure 3—Specialized Registry Reporting.</i> —The EP is in active engagement with a public health agency to submit data to a specialized registry.		
	The eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT except where prohibited and in accordance with applicable law and practice.	Stage 1 eligible hospitals and CAHs must meet at least 2 measures in 2015, Stage 2 eligible hospitals and CAHs must meet at least 3 measures in 2015, all eligible hospitals and CAHs must meet at least 3 measures in 2016 and 2017. <ul style="list-style-type: none"> <i>Measure 1—Immunization Registry Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data. <i>Measure 2—Syndromic Surveillance Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data. <i>Measure 3—Specialized Registry Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit data to a specialized registry. <i>Measure 4—Electronic Reportable Laboratory Result Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit ELR results. 	1 minute	1 minute.
Time to Attest to Objectives and Measures.	6 hours 49 minutes	6 hours 48 minutes.
Time to Attest and Report Clinical Quality Measures.	1 hour 30 minutes	1 hour 30 minutes.
Total—Objectives +CQM Reporting.	8 hours 19 minutes	8 hours 18 minutes.

We estimate that it will take no longer than 6 hours 49 minutes for an EP to attest to each of the applicable objectives and associated measures. The total burden hours for an EP to attest to the meaningful use objectives and measures and to report CQMs will be 8 hours 19 minutes. We estimate that

there could be approximately 595,100 non-hospital-based Medicare EPs in 2015. Based on the historical data, we anticipate approximately 60 percent (357,060) of these EPs may attest to the objectives and measures of meaningful use. In addition, we believe approximately 30,000 Medicaid only

EPs, or approximately 51 percent of the Medicaid-only EPs, will successfully demonstrate meaningful use in 2015. The total estimated annual cost burden for all EPs to attest to meaningful use would be \$297,076,291 (387,060 × 8 hours 19 minutes × \$92.25 (mean hourly rate for physicians based on May 2013

BLS data)). Similarly, eligible hospitals and CAHs will attest that they have met the meaningful use objectives and associated measures, and would submit the clinical quality measures. We estimate that it will take no longer than 6 hours 48 minutes to attest to each of the applicable objectives and associated measures. Therefore, the total burden hours for an eligible hospital or CAH to attest to the meaningful use objectives and measures and to report CQMs, will be 8 hours 18 minutes. We estimate that there are about 4,900 eligible hospitals and CAHs that may attest to the aforementioned criteria in FY 2015 of which 95 percent are expected to demonstrate meaningful use. The total

estimated annual cost burden for all eligible hospitals and CAHs to attest to meaningful use would be \$2,451,872 (4,655 eligible hospitals and CAHs × \$63.46 (8 hours 18 minutes × \$63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)).

We provide the estimate of the burden for the approximately 13,635 MA Eps in the MA organization burden section. The total annual burden estimates for meaningful use for modifications for 2015 through 2017 are shown in Table 23.

For the purpose of this collection of information, we assumed that all eligible providers will comply with the requirements of Meaningful Use as

previously defined if the policies proposed in this rule were not finalized. Therefore, we estimate that the policies contained herein will result in an overall reduction in the reporting burden for providers of 1.45 hours to 1.9 hours for EPs and 2.62 hours for eligible hospitals and CAHs per respondent. While batch reporting for objectives and measures and group reporting for CQMs are available for EPs in the current program; the program is based upon successful individual provider demonstration of meaningful use and so individual totals are used to identify the estimated reduction in provider reporting burden. This reduction of burden is outlined in Table 23.

TABLE 23—REDUCTION IN REPORTING BURDEN HOURS

Burden under current program and proposed modifications	Estimated burden per respondent EPs	Estimated burden per respondent eligible hospitals and CAHs
Total Under Current Stage 2 Requirements at 42 CFR 495.6 Core Set (including CQMs) + Least Burdensome Menu Set Criteria.	9 hours 46 minutes	NA.
Total Under Current Stage 2 Requirements at 42 CFR 495.6 Core Set (including CQMs) + Most Burdensome Menu Set Criteria.	10 hours 13 minutes	10 hours 55 minutes.
Total Under Proposed Modifications at 495.22	8 hours 19 minutes	8 hours 18 minutes.
All Objectives and Measures + CQMs		
Reduction from Least Burdensome Estimate	1 hour 27 minutes	NA.
Reduction from Most Burdensome Estimate	1 hour 54 minutes	2 hour 37 minutes.

Using the hourly costs associated with the reporting burden as mentioned previously, this reduction of 1.45 hours to 1.9 hours for EPs and 2.62 hours for eligible hospitals and CAHs represents a

per response savings of \$133.76 to \$175.28 for EPs and \$166.27 for eligible hospitals and CAHs. The total cost reduction in cost for providers demonstrating meaningful use is

estimated at \$48,534,332 at the lowest and \$63,359,464 at the highest. These estimates are further outlined in Table 24.

TABLE 24—REDUCTION IN BURDEN COST SAVINGS

Number of responses	Burden reduction hours	Hourly cost	Reduction per respondent	Total cost reduction
387,060	1.45	\$92.25	\$133.76	\$51,773,146
387,060	1.9	92.25	175.28	67,843,877
4,655	2.62	63.46	166.27	773,987
Total Least				52,547,132
Total Most				68,617,864

C. ICRs Regarding Qualifying MA Organizations (§ 495.210)

We estimate that the burden will be significantly less for qualifying MA organizations attesting to the meaningful use of their MA EPs, because qualifying MA EPs use the EHR technology in place at a given location or system, so if CEHRT is in place and the qualifying MA organization requires its qualifying MA EPs to use the technology, qualifying MA organizations will be able to determine at a faster rate than individual FFS EPs, that its qualifying MA EPs meaningfully

used CEHRT. In other words, qualifying MA organizations can make the determination in masse if the CEHRT is required to be used at its facilities, whereas under FFS, each EP likely must make the determination on an individual basis. We further note that these differences also mean the total reduction in burden for MA organizations resulting from the modifications in this rule will be negligible. We estimate that, on average, it will take an individual 45 minutes to collect information necessary to determine if a given qualifying MA EP

has met the meaningful use objectives and measures, and 15 minutes for an individual to make the attestation for each MA EP. Furthermore, the individuals performing the assessment and attesting will not likely be the eligible professional, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 11, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately \$25.00/hour, and the person attesting (and who may bind the qualifying MA organization based on the attestation)

could be equivalent to a GS 15, step 1 (2015 unadjusted for locality rate), or approximately \$50.00/hour. Therefore, for the estimated 13,635 potentially qualifying MA EPs with assumed 100 percent successfully demonstrating meaningful use, we believe it will cost the participating qualifying MA organizations approximately \$426,050 annually to collect the required information and make the attestations ([10,226 hours × \$25.00]+[3,408 hours × \$50.00]).

D. ICR Regarding State Reporting Requirements (§ 495.316 and § 495.352)

We are revising 42 CFR 495 regarding state reporting requirements to CMS. With respect to the annual reporting requirements in § 495.316 and the quarterly reporting requirements in § 495.352, we do not believe that the amendments to these reporting

requirements will increase the burden on states beyond what was previously finalized under OMB control number 0938–1158 following the Stage 2 final rule. The deadlines will be consistent with our past practice, and the changes to the data elements to be reported on are either reduced or similar in burden. Similarly, we do not expect that the amendments regarding the 90-day EHR reporting period for first time meaningful users will impose a burden on states because those amendments would generally maintain the current policy.

However, we are also amending § 495.316 to include a new quarterly reporting requirement. States will report quarterly to CMS regarding the EPs and Medicaid eligible hospitals that have successfully demonstrated meaningful use for each payment year. We need this information to ensure that those EPs

who are meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment. We cannot accurately exempt these providers using the current data received from states. We expect that it will take a state 20 hours each year to submit this report on a quarterly basis. We believe that the state employee reporting the information could be equivalent to a GS 12, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately \$30.00/hour. This amount is then reduced by the 90 percent federal contribution for administrative services for Medicaid under the EHR Incentive Programs; this equates to approximately \$3.00/hour. Therefore, for all state Medicaid agencies to report 4 times per year at 20 hours per report the estimated cost is \$13,460 (4560 hours × \$3.00/hour).

TABLE 25—ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Reg section	OMB control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total cost (\$)
§ 495.x—Objectives/ Measures (EPs)	0938–1158	609,100	609,100	6.86	4,178,426	92.25	385,834,395
§ 495.6—Objectives/ Measures (hospitals/ CAHs)	0938–1158	4,900	4,900	6.86	33,614	63.46	2,135,204
§ 495.210—Gather information for attestation (MA EPs)	0938–1158	13,635	13,635	0.75	10,226	25.00	255,650
§ 495.210—Attestation on behalf of MA EPs	0938–1158	13,635	13,635	0.25	3408.75	50.00	170,400
§ 495.316—Quarterly Reporting	0938–1158	56	224	20	4480	3.00	13,440
Totals		627,635	627,635		4,225,674		388,408,189

Notes: 1. All non-whole numbers in this table are rounded to 2 decimal places.
 2. There are no capital/maintenance costs associated with the information collection requirements contained in this rule. Therefore, we removed the associated column from Table 22.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period will implement the provisions of the American Recovery and Reinvestment Act (ARRA) of 2009 that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use CEHRT. This final rule with comment period specifies applicable criteria for demonstrating the Stage 3 requirements for the EHR Incentive Programs. This final rule with comment period also specifies the applicable criteria for an EHR reporting period in 2015 through 2017.

B. Overall Impact

We have examined the impacts of this final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).
 Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory

alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule with comment period is anticipated to have an annual effect on the economy of \$100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that presents the estimated costs and benefits of this final rule with comment period.

The portion of the final rule related to Stage 3 is one of two coordinated rules related to the EHR Incentive Programs. The other is ONC's 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications. Thus, there is an analysis that focuses on the impact associated with Stage 3 requirements for the EHR Incentive Program, the changes in quality measures that would take effect beginning in 2017, and other changes being for the Medicare and Medicaid EHR Incentive Programs.

As we discussed in the Stage 2 final rule (77 FR 54163 through 54291), a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. In this final rule with comment period, we continue to believe that a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. Readers should understand that these forecasts are also subject to substantial uncertainty since meeting the requirements of the program will depend not only on the standards and requirements for 2017 and for eligible hospitals and EPs, but on future rules issued by the Department of Health and Human Services (DHHS).

Based on the Stage 2 final rule, we expect spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2015 and 2017 to be \$14.2 billion. However, the policies in this final rule with comment period which are applicable for the EHR Incentive Programs in 2015 through 2017 do not change these estimates over the current period as the proposals in the EHR Incentive Programs in 2015 through 2017 proposed rule applied no changes to the payment of incentives or the application of payment adjustments for 2015 through 2017.

Our analysis of impacts for the policies in this final rule with comment period relate to the reduction in cost associated with provider reporting burden estimates for 2015 through 2017 as affected by the adopted changes to the current program and to the transfer payments for incentives for Medicaid providers and reductions in payments for Medicare providers through payment adjustments for 2018 and subsequent years. In the Stage 3 proposed rule, we noted our expectation that spending under the EHR Incentive Program for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be \$3.7 billion (this estimate

includes net payment adjustments for Medicare providers who do not achieve meaningful use in the amount of \$0.8 billion).

We stated in the Stage 2 final rule (77 FR 54135 through 54136) that the statute provides Medicare and Medicaid incentive payments for the meaningful use of CEHRT. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. Beginning in 2015, payment adjustments are incorporated into the Medicare EHR Incentive Program for providers unable to demonstrate meaningful use. The absolute and relative strength of these is unclear. For example, a provider with relatively small Medicare billings will be less affected by payment adjustments than one with relatively large Medicare billings. Another uncertainty arises because there are likely to be "bandwagon" effects as the number of providers using EHRs rises, thereby inducing more participation in the program, as well as greater adoption by entities (for example, clinical laboratories) that are not eligible for incentives or subject to payment adjustments, but do business with EHR adopters. It is impossible to predict exactly if and when such effects may take hold.

All of these factors taken together make it impossible in this final rule with comment period to predict with precision the timing or rates of adoption and successful participation in the program. However, new data is currently available regarding rates of adoption or costs of implementation since the publication of our Stage 1 and Stage 2 final rules. We have included the new data in our estimates, although even these forecasts are still uncertain.

We have also estimated "per entity" costs for EPs, eligible hospitals, and CAHs for implementation/maintenance and reporting requirement costs, not all costs. We believe many adopting entities may achieve dollar savings at least equal to their total costs, and that there may be additional benefits to society. We also believe that implementation costs are significant for each participating entity because providers who were likely to qualify as meaningful users of EHRs were likely to purchase CEHRT. However, we believe that providers who have already purchased CEHRT and participated in Stage 1 or Stage 2 of the EHR Incentive Program will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs of the program may be outweighed by the long-term

benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, the RIA that we have prepared presents the estimated costs and benefits of this final rule with comment period.

In addition, we include the impact of the EHR Incentive Programs in 2015 through 2017. In relation to the existing program requirements outlined in the Stage 2 final rule (77 FR 53967 through 54162), we do not expect this final rule with comment period to result in more incentives paid or in more providers failing meaningful use and being assessed a payment adjustment. This is due to the nature of the modifications being implemented by this rule, which, while they reduce the reporting burden on providers, do not affect the clinical processes and IT functions required to meet the objectives and measures of the EHR Incentive Programs. The provisions of the modifications portion in this final rule with comment period do not fundamentally change the technology required to support participation in the Medicare and Medicaid EHR Incentive Programs. Under the current program, the requirement to report data on the measures and objectives which have now been identified as redundant to other more advanced measures being retained, or are duplicative of other measures using the same CEHRT function, is essentially requiring providers to report on the same action or process twice. Therefore, it is not the occurrence of the action or process which is reduced by the provisions in this final rule with comment period, but the burden associated with the duplicative and redundant reporting. In addition, the objectives and measures, which are considered topped out, have reached high performance and the statistical evidence demonstrates that the expected result of any provider attesting to the EHR Incentive Programs would be a score near the maximum. However, the analysis of these measures and their identification as topped out also takes into account the statistical likelihood that the functions of measures and the processes behind them would continue even without a requirement to report the results. Therefore, while the provisions result in a reduction in reporting requirements, this does not correlate to a change in the overall achievement of the measures and objective as compared to the current program. Finally, when compared against historical data, the shortened EHR reporting period in 2015 is expected to have a minimal impact on successful demonstration of meaningful

use. This expectation of minimal impact is based on a number of factors:

- The shortened EHR reporting period is for 2015 only and not for 2016 or 2017.

- Historical data on attestations shows no strong correlation between a shorter EHR reporting period and the ability of providers to attest for a second year, no correlation for providers returning to attest to a third or fourth year of meaningful use, and providers who would otherwise be in their first year of meaningful use would already have a 90-day EHR reporting period.²²

- Performance data shows statistically negligible disparity among providers attesting for a 90-day EHR reporting period and those attesting for a full year EHR reporting period on the measures which have been identified as redundant, duplicative, and topped out.²³

For these reasons, we do not believe the modification provisions in this final rule with comment period will impact the overall estimates for incentive payments, payment adjustments, and the net transfer costs associated with the program. However, these provisions do affect the costs associated with the reporting burden on providers. The impacts directly attributable with the provisions in this final rule with comment period relate to both an hourly reduction per response and an overall reduction in the cost associated with provider reporting. The burden analysis for modifications in this final rule with comment period, as compared to the Stage 2 estimates, reduces the reporting burden for attestation for providers by approximately 1.45 hours to 1.9 hours for EPs and 2.62 hours for eligible hospitals and CAHs per respondent. This burden estimate and analysis of the impact of the policies result in a total cost reduction estimated at \$48,534,332 at the lowest and \$63,359,464 at the highest. However, we believe the modifications portion of this final rule with comment period will have additional impacts—most notably, cost savings for hospitals and providers that would have additional time to meet the requirements of the program—which cannot be adequately estimated because of the wide variation among provider types, and therefore a designation as an

economically significant rule under the Executive Order and a major rule under the Congressional Review Act is still applicable. The burden estimate and analysis of the impact of the policies implemented by the modifications of this final rule with comment period are outlined further in section III. of this final rule with comment period.

C. Anticipated Effects

The objective of the remainder of this final RIA is to summarize the costs and benefits of the HITECH Act incentive program for the Medicare FFS, Medicaid, and MA programs. We also provide assumptions and a narrative addressing the potential costs to the health care industry for implementation of this technology.

1. Overall Effects

a. EHR Technology Development and Certification Costs—Stage 3

We note that the costs incurred by IT developers for EHR technology development and certification to the 2015 Edition certification criteria for health IT are also in part attributable to the requirements for the use of CEHRT established in this final rule with comment period for Stage 3 of the EHR Incentive Programs. Therefore, to the extent that providers' implementation and adoption costs are attributable to this final rule with comment period, health IT developers' preparation and development costs would also be attributable as these categories of activities may be directly or indirectly incentivized by the requirements to participate in the EHR Incentive Programs. However, other CMS programs (for example PQRS and IQR) do require or promote certification to ONC's criteria—or a professional organization or other such entity could require or promote certification to ONC's criteria.²⁴ As noted previously, this analysis focuses on the impact associated with Stage 3 requirements for providers, while the development and certification costs are addressed in the 2015 Edition final rule.

b. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In

the healthcare sector, Small Business Administration (SBA) size standards define a small entity as one with between \$7.5 to \$38.5 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size. Individuals and states are not included in the definition of a small entity. Since the vast majority of Medicare providers (well over 90 percent) are small entities within the RFA's definitions, it is the normal practice of HHS simply to assume that all affected providers are "small" under the RFA. In this case, most EPs, eligible hospitals, and CAHs are either nonprofit or meet the SBA's size standard for small business. We also believe that the effects of the incentives program on many and probably most of these affected entities would be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Final Regulatory Flexibility Analysis (IFRFA). We believe that the adoption and meaningful use of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some EPs and hospitals affiliated with MA organizations. While the program is voluntary, in the first 5 years it carries substantial positive incentives that make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology for an applicable EHR reporting period will be subject to significant Medicare payment reductions beginning in 2015. These Medicare payment adjustments are expected to motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs, CAHs, and eligible hospitals, the EHR technology currently implemented could be upgraded to meet the criteria for CEHRT as defined for this program. These costs may be minimal, involving no more than a software upgrade. "Home-grown" EHR systems that might exist may also require an upgrade to meet the certification requirements. We believe many currently used non-certified EHR systems will require significant changes to achieve certification and that EPs, CAHs, and eligible hospitals will have to make process changes to achieve meaningful use.

Data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. An ONC data brief (No. 16, May 2014) noted that hospital adoption of EHR systems has increased 5 fold since

²² CMS Data and Reports: Quarterly Public Use Files for participation, Monthly Reports for performance rates: <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>

²³ CMS Data and Reports: Quarterly Public Use Files for participation, Monthly Reports for performance rates: <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>

²⁴ In this case, the provider implementation and adoption costs discussed in this CMS RIA would instead be attributable to ONC's rulemaking.

2008. Nine in 10 acute care hospitals possessed CEHRT in 2013, increasing 29 percent since 2011. As of January 1, 2015, more than 95 percent of eligible hospitals had successfully demonstrated meaningful use. In January 2014, a CDC data brief entitled, "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001 through 2013," found that 78 percent of office-based EPs used any type of EHR systems, up from 18 percent in 2001. The majority of EPs have already purchased CEHRT, implemented this new technology, and trained their staff on its use with over 60 percent earning an incentive payment for participation in the program prior to 2015. The costs for implementation and complying with the criteria of EHR Incentive Programs could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency may compensate for some of the initial expenditures. Furthermore, the cost reductions provided by the EHR Incentive Programs in 2015 through 2017 offer a benefit to these providers.

(1) Small Entities

We estimate that EPs would spend approximately \$54,000 to purchase and implement a certified EHR and \$10,000 annually for ongoing maintenance according to the Congressional Budget Office (CBO) (75 FR 44546).

In the paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, the CBO recognized the complicating factors of EHR types, available features and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of \$25,000 to \$45,000 per physician. Annual operating and maintenance amount was estimated at 12 to 20 percent of initial costs (that is, \$3,000 to \$9,000) per physician. For all eligible hospitals, the range is from \$1 million to \$100 million. Though reports vary widely, we anticipate that the average will be \$5 million for eligible hospitals to achieve meaningful use. We estimate \$1 million for maintenance, upgrades, and training each year per eligible hospital. However, as stated earlier, many providers have already purchased systems with expenditures focused on maintenance and upgrades. We believe that future retrospective studies on the costs to implement and EHR and the return on investment (ROI) will demonstrate the actual costs incurred by providers participating in

the EHR Incentive Programs. The potential costs savings in modifications to the EHR Incentive Programs portion of this final rule with comment period will benefit these providers as a reduction in the overall cost of program participation.

(2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers. We believe that the net effect on some individual providers may be positive. Furthermore, we believe that the provisions in this EHR Incentive Programs in 2015 through 2017 portion of this final rule with comment period will result in an overall reduction in the reporting burden for providers of all types. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this final rule with comment period.

c. Small Rural Hospitals—Modifications

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds.

The Stage 3 portion of this final rule with comment period will affect the operations of a substantial number of small rural hospitals because they may be subject to adjusted Medicare payments in 2015 if they fail to adopt CEHRT by the applicable EHR reporting period. As stated previously, we have determined that this final rule with comment period will create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of CEHRT in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors. However, the Secretary retains the discretionary statutory authority to make case-by-case exceptions for significant hardships, and has already established certain categories where case-by-case applications may be made such as barriers to Internet connectivity that impact health information exchange.

There is no identifiable disparity among this group and the overall success rates for eligible hospitals and CAHs in meeting the requirements of the program; furthermore, 95 percent of eligible hospitals and CAHs have successfully participated as of January 1, 2015. Finally, on the whole we anticipate an estimated reduction in the reporting burden on eligible hospitals as a group to be less than \$1 million. Therefore, we do not believe that the modifications portion of this final rule with comment period will have a significant impact on a substantial number of small entities.

d. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will require spending in any 1 year \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$144 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "federal mandate" costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This final rule with comment period imposes no substantial mandates on states. This program is voluntary for states and states offer the incentives at their option. The state role in the incentive program is essentially to administer the Medicaid EHR Incentive Program. While this entails certain procedural responsibilities, these do not involve substantial state expense. In general, each state Medicaid Agency that participates in the incentive program would be required to invest in systems and technology to comply. States would have to identify and educate providers, evaluate their attestations and pay the incentive. However, the federal government would fund 90 percent of the state's related administrative costs, providing controls on the total state outlay. In addition, the changes being made by the modifications portion of this final rule with comment period have very little impact on any state functions.

The investments needed to meet the requirements of the program and obtain incentive funding are voluntary, and hence not "mandates" within the meaning of the statute. However, the potential reductions in Medicare reimbursement beginning with FY 2015

would have a negative impact on providers that fail to meaningfully use CEHRT for the applicable EHR reporting period. We note that we have no discretion as to the amount of those potential payment reductions. Private sector EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed \$141 million. However, because EPs may choose for various reasons not to participate in the program, we do not have firm data for the percentage of participation within the private sector. This RIA, taken together with the remainder of the preamble, constitutes the analysis required by UMRA.

e. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule with comment period will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication. Importantly, state Medicaid agencies are receiving 100 percent match from the federal government for incentives paid and a 90 percent match for expenses associated with administering the program. As previously stated, we believe that state administrative costs are minimal.

We note that the Stage 3 portion of this final rule with comment period does add a new business requirement for states, because of the existing systems that would need to be modified to track and report on the new requirements of the program for provider attestations. We are providing 90 percent Federal Financial Participation (FFP) to states for modifying their existing EHR Incentive Program systems. We believe the federal share of the 90 percent match will protect the states from burdensome financial outlays and, as noted previously, states offer the Medicaid EHR incentive program at their option.

The modifications portion of this final rule with comment period will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication.

2. Effects on EPs, Eligible Hospitals, and CAHs

a. Background and Assumptions

Based on the actual count of provider's eligible for the program as of

December 31, 2014 which were identified through the process of implementing payment adjustments for 2015, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA for 2015 through 2017 and used the updated estimates throughout the analysis. These total potential eligible providers are as follows:

- About 660,000 Medicare FFS EPs (some of whom will also be Medicaid EPs).
- About 595,100 non-hospital based Medicare EPs.
- About 58,300 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners, and physicians assistants).
- 4,900 eligible hospitals comprising the following:
 - ++ 3,397 acute care hospitals.
 - ++ 1,395 CAHs.
 - ++ 97 children's hospitals (Medicaid only).
 - ++ 11 cancer hospitals (Medicaid only).
 - 16 MA organizations and 13,635 MA EPs

(1) EHR Incentive Programs in 2015 Through 2017

There are no new costs associated with the modifications portion of this final rule with comment period. Furthermore, the estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are somewhat uncertain for the following reasons:

- The program is voluntary although payment adjustments will be imposed on Medicare providers if they are unable to meet the requirements of the program for the applicable EHR reporting period.
- The potential reduction in burden for EPs relate to assumptions of what options for meeting the requirements of the program they would otherwise attest to should the policies in this final rule with comment period not be adopted.
- The net costs and savings for any individual provider may not directly correlate to the total for the organization as larger organizations may employ economies of scale in EHR attestations.

(2) Stage 3

The principal costs of the Stage 3 portion of final rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicaid incentive payments to adopt, implement or upgrade and demonstrate (or both) meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will

ensue if they fail to do so. The estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are uncertain for the following reasons:

- The program is voluntary although payment adjustments will be imposed on Medicare providers beginning in 2015 if they are unable to demonstrate meaningful use for the applicable EHR reporting period.
- The criteria for the demonstration of meaningful use of CEHRT has been finalized for Stage 1 and Stage 2 and is being finalized for Stage 3, but may change over time.
- The impact of the financial incentives and payment adjustments on the rate of adoption of CEHRT by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected.

b. Industry Costs and Adoption Rates

(1) Modifications

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we proposed no new policies which would require changes to the development, certification, and implementation of CEHRT or to adoption rates as compared to the policies in the existing program outlined in the Stage 2 final rule (77 FR 54136 through 54146).

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the policies in this proposed rule with certainty. We believe the assumptions and methods described herein are reasonable for estimating the financial impact of the provisions on providers participating in the Medicare and Medicaid programs, but acknowledge the wide range of possible outcomes.

(a) Medicare Eligible Professionals (EPs)

In brief, the estimates of Medicare EP burden reduction are based on current participation as of January 1, 2015. We estimate that significant cost reductions for Medicare EPs participating in the EHR Incentive Program will result from the policies in this final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are presented in Table 27. They reflect our assumptions about the proportion of EPs who will demonstrate meaningful use of CEHRT outlined in Table 26 based on historical data.

TABLE 26—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CEHRT

	Calendar Year		
	2015	2016	2017
Medicare EPs who have claims with Medicare (in thousands)	660.0	667.8	675.5
Nonhospital-based Medicare EPs (in thousands)	595.1	602.1	609.1
Percent of EPs who are Meaningful Users	60	65	70
Meaningful Users (in thousands)	357.1	391.4	426.4

TABLE 27—ESTIMATED COST REDUCTION FOR MEDICARE EPS

	Calendar Year		
	2015	2016	2017
Meaningful Users (in thousands)	357.1	391.4	426.4
Lowest Estimated Cost Savings	\$47,760,345.60	\$52,353,664.00	\$57,035,264.00
Highest Estimated Cost Savings	\$62,585,476.80	\$68,604,592.00	\$74,739,392.00

(b) Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital burden reduction are based on current participation as of January 1, 2015. We estimate that significant cost reductions

for Medicare eligible hospitals and CAHs participating in the EHR Incentive Program will result from the policies in this final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are

presented in Table 29. They reflect our assumptions about the proportion of eligible hospitals and CAHs that will demonstrate meaningful use of CEHRT outlined in Table 28 based on historical data.

TABLE 28—MEDICARE ELIGIBLE HOSPITALS AND CAHs DEMONSTRATING MEANINGFUL USE OF CEHRT

	Calendar Year		
	2015	2016	2017
Eligible Hospitals	3397	3397	3397
CAHs	1395	1395	1395
Percent Demonstrating Meaningful Use	95	97	99
Meaningful Users	4552	4648	4744

TABLE 29—ESTIMATED COST REDUCTION FOR MEDICARE ELIGIBLE HOSPITALS AND CAHs

	Calendar Year		
	2015	2016	2017
Meaningful Users	4552	4648	4744
Estimated Cost Savings	\$756,861.04	\$772,822.96	\$788,784.88

(c) Medicaid Only EPs

We estimate that significant cost reductions for Medicaid only EPs participating in the EHR Incentive Program will result from the policies in

this final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are presented in Table 31. They reflect our

assumptions about the proportion of Medicaid only EPs who will demonstrate meaningful use of CEHRT outlined in Table 30 based on historical data.

TABLE 30—MEDICAID ONLY EPs DEMONSTRATING MEANINGFUL USE

	Calendar Year		
	2015	2016	2017
Medicaid only EPs	58.3	59.4	60.6
Percent of EPs who are Meaningful Users	51	53	55
Meaningful Users (in thousands)	30	31.48	33.33

TABLE 31—ESTIMATED COST REDUCTION FOR MEDICAID ONLY EPS

	Calendar Year		
	2015	2016	2017
Meaningful Users (in thousands)	30,000	31,480	33,330
Lowest Estimated Cost Savings	\$4,012,800.00	\$4,210,764.80	\$4,458,220.80
Highest Estimated Cost Savings	\$5,258,400.00	\$5,517,814.40	\$5,842,082.40

It should be noted that since the Medicaid EHR Incentive Program provides that a Medicaid EP can receive an incentive payment in their first year because he or she has demonstrated meaningful use or because he or she has adopted, implemented, or upgraded CEHRT, these participation rates include only those Medicaid providers who are expected to demonstrate meaningful use. Providers who are dual-eligible have been included in the Medicare EP program estimates based

on the total current volume of Medicare EPs who have demonstrated meaningful use in either Medicare or Medicaid as of January 1, 2015.

(d) Medicaid Only Hospitals

The burden reduction for Medicaid only eligible hospitals assumes a similar participation rate for the demonstration of meaningful use as is applicable for Medicare eligible hospitals. We estimate that significant cost reductions for Medicaid only eligible hospitals

participating in the EHR Incentive Program will result from the policies in this final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are presented in Table 33. They reflect our assumptions about the proportion of Medicaid only eligible hospitals that will demonstrate meaningful use of CEHRT outlined in Table 32 based on historical data.

TABLE 32—MEDICAID ONLY ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CEHRT

	Calendar year		
	2015	2016	2017
Eligible Hospitals	108	108	108
Percent Demonstrating Meaningful Use	95	97	99
Meaningful Users	103	105	107

TABLE 33—ESTIMATED COST REDUCTION FOR MEDICARE ELIGIBLE HOSPITALS AND CAHS

	Calendar year		
	2015	2016	2017
Meaningful Users	4552	4648	4744
Estimated Cost Savings	\$17,125.81	\$17,458.35	\$17,790.89

(2) Stage 3

In the Stage 2 final rule (77 FR 54136 through 54146), we estimated the impact on healthcare providers using information from four studies. In the absence of any more recent estimates that we are aware of, in this final rule with comment period, we continue to use the same estimates cited in the Stage 2 final rule. We continue to believe that these estimates are reasonably reflective of EHR costs. However, we note, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the final rule; the variability includes, but is not limited to, the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and upgrading systems or both. Based on these studies and current average costs for available CEHRT products, we continue to estimate for

EPs that the average adopt/implement/upgrade cost is \$54,000 per physician FTE, while annual maintenance costs average \$10,000 per physician FTE.

For all eligible hospitals, we continue to estimate the range is from \$1 million to \$100 million. Although reports vary widely, we continue to anticipate that the average will be \$5 million to achieve meaningful use, because providers who will likely qualify as meaningful users of EHRs will need to purchase certified EHRs. We further acknowledge “certified EHRs” may differ in many important respects from the EHRs currently in use and may differ in the functionalities they contain. We continue to estimate \$1 million for maintenance, upgrades, and training each year. Both of these estimates are based on average figures provided in the 2008 CBO report. However, as noted previously, we are unable to delineate all costs due to the great variability in characteristics among the entities that

are affected by the final rule; the variability includes, but is not limited to, the size of the hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and upgrading systems or both.

Industry costs are important, in part, because EHR adoption rates will be a function of these industry costs and the extent to which the costs of “certified EHRs” are higher than the total value of EHR incentive payments available to EPs and eligible hospitals (as well as adjustments, in the case of the Medicare EHR incentive program) and any perceived benefits including societal benefits. Because of the uncertainties surrounding industry cost estimates, we have made various assumptions about adoption rates in the following analysis in order to estimate the budgetary impact on the Medicare and Medicaid programs.

c. Costs of EHR Adoption for EPs

Since the publication of the Stage 1 final rule, there has been little data published regarding the cost of EHR adoption and implementation. A 2011 study (<http://content.healthaffairs.org/content/30/3/481.abstract>) estimated costs of implementation for a five-physician practice to be \$162,000, with \$85,500 in maintenance expenses in the first year. In the absence of additional data regarding the cost of adoption and implementation costs for certified EHR technology, we proposed to continue to estimate for EPs that the average adopt/implement/upgrade cost is \$54,000 per physician FTE, while annual maintenance costs average \$10,000 per physician FTE, based on the cost estimate of the Stage 1 final rule. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and upgrading systems or both.

d. Costs of EHR Adoption for Eligible Hospitals

According to the American Hospital Association 2008 Survey, the range in yearly information technology spending among hospitals ranged from \$36,000 to over \$32 million. EHR system costs specifically were reported by other experts to run as high as \$20 million to \$100 million (77 FR 54139). We note that recently about 96 percent of eligible hospitals have received at least one incentive payment under either the

Medicare or Medicaid programs. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the eligible hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and upgrading systems or both.

3. Medicare and Medicaid Incentive Program Costs for Stage 3

Based on input from a number of internal and external sources, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA expected to be eligible for the program in 2017 and used these estimates for the following analysis of Stage 3 program costs.

- About 675,500 Medicare FFS EPs in 2017 (some of whom will also be Medicaid EPs).
- About 60,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners, and physician assistants) could be eligible to receive the Medicaid incentive payments in 2017.
- 4,900 eligible hospitals comprising the following:
 - ++ 3,397 acute care hospitals
 - ++ 1,395 CAHs
 - ++ 97 children’s hospitals (Medicaid only)
 - ++ 11 cancer hospitals (Medicaid only)
- All eligible hospitals, except for children’s and cancer hospitals, may qualify and apply for both Medicare and Medicaid incentive payments.

- About 16 MA organizations

a. Medicare Program Costs for Stage 3

The estimates for the HITECH Act provisions are based on the economic assumptions underlying the President’s FY 2016 Budget. Under the statute, Medicare incentive payments for CEHRT are excluded from the determination of MA capitation benchmarks. We continue to expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid because of the implementation of EHR technology.

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the HITECH Act with great certainty. We believe the assumptions and methods described herein are reasonable for estimating the financial impact of the provisions on the Medicare and Medicaid programs, but acknowledge the wide range of possible outcomes.

(1) Medicare Eligible Professionals (EPs)

We began making EHR Incentive payments in 2011. Medicare payments are to be paid for the successful demonstration on meaningful use through CY 2016. Due to the payment lag, some payments may be issued in CY 2017. To avoid the Medicare payment adjustment beginning in 2015, EPs need to successfully demonstrate meaningful use regardless of whether they earn an incentive payment. We estimated the percentage of the remaining EPs who would be meaningful users each calendar year. Table 34 shows the results of these calculations.

TABLE 34—MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CEHRT

	Calendar year			
	2017	2018	2019	2020
Medicare EPs who have claims with Medicare (thousands)	675.5	683.3	691.1	698.8
Non-Hospital-based Medicare EPs (thousands)	609.1	616.1	623.1	630.1
Percent of EPs who are Meaningful Users	70	73	75	78
Meaningful Users (thousands)	426.4	446.7	467.3	488.3

Our estimates of the incentive payment costs and payment adjustment savings are presented in Table 35. They reflect actual historical data and our assumptions about the proportion of EPs who will demonstrate meaningful use of

CEHRT. Estimated costs are expected to decrease in 2017 through 2020 due to a smaller number of new EPs that would achieve meaningful use and the cessation of the incentive payment program. Payment adjustment receipts

represent the estimated amount of money collected due to the payment adjustments for those not achieving meaningful use. Estimated net costs for the Medicare EP portion of the HITECH Act are also shown in Table 35.

TABLE 35—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CEHRT
[in billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	\$0.6	– \$0.2	\$0.3
2018	– 0.2	– 0.2
2019	– 0.2	– 0.2
2020	– 0.1	– 0.1

(2) Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments and then making assumptions about how rapidly hospitals would adopt meaningful use.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine how many eligible hospitals already received payments under the EHR Incentive program and for what years those payments were received. In order to do this, we used the most recent available data that listed the recipients of incentive payments, and the year and payment amount. This information pertained to eligible hospitals receiving payments through September 2014.

We assume that all eligible hospitals that receive a payment in the first year will receive payments in future years. We also assume the eligible hospitals that have not yet received any incentive payments will eventually achieve meaningful use (either to receive incentive payments or to avoid payment adjustments). We assume that all

eligible hospitals would achieve meaningful use by 2018. No new incentive payments would be paid after 2016. However, some incentive payments originating in 2016 would be paid in 2017.

The average incentive payment for each eligible hospital was \$1.5 million in the first year. In later years, the amount of the incentive payments drops according to the schedule allowed in law. The average incentive payment for CAHs received in the first year was about \$950,000. The average incentive payment received in the second year was about \$332,500. The average incentive payment received in the third year was about \$475,000. These average amounts were used for these incentive payments in the future. The third year average was also used for the fourth year. These assumptions about the number of hospitals achieving meaningful use in a particular year and the average amount of an incentive payment allows us to calculate the total amount of incentive payments to be made and the amount of payment adjustments for those hospitals who have not achieved meaningful use. The

payment incentives available to hospitals under the Medicare and Medicaid EHR Incentive Programs are included in our regulations at 42 CFR part 495. We further estimate that there are 16 MA organizations that might be eligible to participate in the incentive program. Those plans have 32 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

The estimated payments to eligible hospitals were calculated based on the hospitals' qualifying status and individual incentive amounts under the statutory formula. Similarly, the estimated payment adjustments for non-qualifying hospitals were based on the market basket reductions and Medicare revenues. The estimated savings in Medicare eligible hospital benefit expenditures resulting from the use of hospital certified EHR systems were discussed earlier in this section. We assumed no future growth in the total number of hospitals in the U.S. because growth in acute care hospitals has been minimal in recent years. The results are shown in Table 36.

TABLE 36—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CEHRT
[in billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	\$1.6	(¹)	(¹)	\$1.6
2018	0.0	(¹)	(¹)	(¹)
2019	0.0	0.0	(¹)	(¹)
2020	0.0	0.0	(¹)	(¹)

¹ Savings of less than \$50 million. All numbers are projections.

b. Medicaid Incentive Program Costs for Stage 3

Under section, 4201 of the HITECH Act, states and territories can voluntarily participate in the Medicaid EHR Incentive Program. However, as of

the writing of this rule, all states already participate. The payment incentives available to EPs and eligible hospitals under the Medicaid EHR Incentive Program are included in our regulations at 42 CFR part 495. The federal costs for Medicaid incentive payments to

providers who can demonstrate meaningful use of EHR technology were estimated similarly to the estimates for Medicare eligible hospitals and EPs. Table 37 shows our estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 37—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID
[in billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2017	0.4	0.8	(1)	1.2
2018	0.1	0.5	(1)	0.6
2019	0	0.3	(1)	0.3
2020	0.0	0.2	(1)	0.2

¹ Savings of less than \$50 million.

(1) Medicaid EPs

TABLE 38—ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPs WHO WOULD BE MEANINGFUL USERS OF CEHRT
[Population figures in thousands]

		Calendar year			
		2017	2018	2019	2020
A	EPs who meet the Medicaid patient volume threshold	101.3	102.3	103.3	104.4
B	Medicaid only Eps	60.6	61.7	62.9	64.0
	Total Medicaid EPs (A+B)	161.8	164.0	166.2	168.4
	Percent of EPs receiving incentive payment during year	44.7	30.9	20.7	14.3
	Number of EPs receiving incentive payment during year	72.4	50.7	34.5	24.0
	Percent of EPs who have ever received incentive payment	67.9	74.7	78.0	81.1
	Number of EPs who have ever received incentive payment	109.9	122.5	129.6	136.6

It should be noted that since the Medicaid EHR Incentive Program provides that a Medicaid EP can receive an incentive payment in his or her first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded CEHRT, these participation rates include not only meaningful users but eligible providers implementing CEHRT as well.

(2) Medicaid Hospitals

Medicaid incentive payments to most eligible hospitals were estimated using the same methodology as described previously for Medicare eligible hospitals and shown in Table 39. Many eligible hospitals may qualify to receive both the Medicare and Medicaid incentive payment. We assume that all eligible hospitals would achieve meaningful use by 2016. However, many of these eligible hospitals would have already received the maximum amount of incentive payments. Table 40 shows our assumptions about the remaining incentive payments to be paid.

TABLE 39—ESTIMATED PERCENTAGE OF HOSPITALS THAT COULD BE PAID FOR MEANINGFUL USE AND ESTIMATED PERCENTAGE PAYABLE BY FISCAL YEAR

Fiscal year	Percent of hospitals who are meaningful users	Percent of hospitals being paid
2017	100.0	13.5
2018	100.0	5.2
2019	100.0	1.5
2020	100.0	0.0

As stated previously, the estimated eligible hospital incentive payments were calculated based on the eligible hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The average Medicaid incentive payment in the first year was \$1 million. The estimated savings in Medicaid benefit expenditures resulting from the use of CEHRT are discussed in section V.C.4 of this final rule with comment period. Since we use Medicare data and little data existed for children's hospitals, we estimated the Medicaid incentives payable to children's hospitals as an add-on to the base estimate, using data on the number of children's hospitals compared to non-children's hospitals.

4. Benefits for All EPs and All Eligible Hospitals

In this final rule with comment period, we did not quantify the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, CEHRT) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC²⁵ found that 92 percent of articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. A subsequent 2013 study completed by the RAND

²⁵ Buntin et al. 2011 "The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results" Health Affairs.

Corporation for ONC²⁶ found 77 percent of articles published between January 2010 to August 2013 that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. Another study, at one hospital emergency room in Delaware, showed the ability to download and create a file with a patient’s medical history saved the ER \$545 per use, mostly in reduced waiting times. A pilot study of ambulatory practices found a positive return on investment within 16 months and annual savings thereafter.²⁷ Another study compared the productivity of 75 providers within a large urban primary care practice over a 4-year period showed increases in productivity of 1.7 percent per month per provider after EHR adoption.²⁸ As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits.

5. Benefits to Society

According to a CBO study, when used effectively, EHRs can enable providers to deliver health care more efficiently.²⁹ For example, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits, and assist in managing complex care. This is consistent with the findings in the ONC study cited previously. Further, the CBO report claims that there is a potential to gain both internal and external savings from widespread adoption of health IT, noting that internal savings will likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the

ability to exchange information more efficiently. However, it is important to note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a potential area of research and analysis that remains unexamined. The benefits resulting specifically from this final rule with comment period are even harder to quantify because they represent, in many cases, adding functionality to existing systems and reaping the network externalities created by larger numbers of providers participating in information exchange. In many cases, they represent the reduction in the time spent per each individual respondent to attest to the EHR Incentive Program objectives and measures. While this time may represent a reduced burden and the opportunity to reallocate resources, there is no viable way to estimate that benefit over a wide range of provider types, practice sizes and other potential variables. For example, the reduction of about 2 hours per respondent for a small practice might be insignificant; however, for a practice of 1,000 providers it may represent as many as 2,000 man hours, which could be reallocated, to making other improvements in clinical processes and patient outcomes. Conversely, a large practice may instead leverage the batch reporting option and only see an overall reduction of 20 man hours as an organization while a small practice may find an even greater reduction than the estimate, which may amount to a significantly increased benefit and more

time for the provider to spend in patient care.

In the Stage 2 final rule at 77 FR 54144, we discussed research documenting the association of EHRs with improved outcomes among diabetics³⁰ and trauma patients,³¹ enhanced efficiencies in ambulatory care settings,³² and improved outcomes and lower costs in hospitals.³³ The 2013 ONC report cited previously reported findings from their literature review on health IT and safety of care, health IT and quality of care, health IT and safety of care, and health IT and efficiency of care in ambulatory and non-ambulatory care settings. The report indicated that a majority of studies that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The report concluded that their findings “suggested that health IT, particularly those functionalities included in the Meaningful Use, can improve healthcare quality and safety. However, data relating specifically to the EHR Incentive Programs is limited at this time.

6. Summary

In this final rule with comment period, the burden estimate and analysis of the impact of the policies result in a total cost reduction estimated at \$48,534,332 at the lowest and \$63,359,464 at the highest for an EHR reporting period on an annual basis for 2015 through 2017. For further information on prior estimates of program costs we direct readers to the Stage 2 final rule (77 FR 54145).

The total cost to the Medicare and Medicaid programs between 2017 and 2020 is estimated to be \$3.7 billion in transfers.

TABLE 40—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)
[in billions]

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2017	\$1.6	\$0.3	\$0.4	\$0.8	\$3.1

²⁶ Shekelle et al. 2013 “Health Information Technology: An Updated Systemic Review with a Focus on Meaningful Use Functionalities.

²⁷ Greiger et al. 2007, A Pilot Study to Document the Return on Investment for Implementing an Ambulatory Electronic Health Record at an Academic Medical Center <http://www.journalacs.org/article/S1072-7515%2807%2900390-0/abstract-article-footnote-1>.

²⁸ DeLeon et al. 2010, “The business end of health information technology”.

²⁹ Congressional Budget Office: “Evidence on the Costs and Benefits of Health Information Technology” <http://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf>.

³⁰ (Hunt, JS et al. (2009) “The impact of a physician-directed health information technology system on diabetes outcomes in primary care: a pre- and post-implementation study” *Informatics in Primary Care* 17(3):165–74; Pollard, C et al. (2009) “Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers” *Journal of Rural Health* 25(1):77–84).

³¹ Deckelbaum, D. et al. (2009) “Electronic medical records and mortality in trauma patients” *The Journal of Trauma: Injury, Infection, and Critical Care* 67(3): 634–636.

³² Chen, C et al. (2009) “The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care.” *Health Affairs* 28(2):323–333.

³³ Amarasingham, R. et al. (2009) “Clinical information technologies and inpatient outcomes: a multiple hospital study” *Archives of Internal Medicine* 169(2):108–14.

TABLE 40—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)—Continued
[in billions]

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2018	0.0	-0.2	0.1	0.5	0.4
2019	0.0	-0.2	0.0	0.3	0.1
2020	0.0	-0.1	0.0	0.2	0.1
Total	1.6	-0.2	0.5	1.8	3.7

D. Alternatives Considered for Stage 3

As stated in the Stage 1 final rule (75 FR 44546), HHS has no discretion to change the incentive payments or payment adjustment reductions specified in the statute for providers that adopt or fail to adopt CEHRT and demonstrate meaningful use of CEHRT. However, we have discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2017 and subsequent years, which we have exercised in this final rule with comment period. Additionally, we have used our discretion to propose the timing of registration, attestation, and payment requirements to allow EPs and eligible organizations as much time as possible in coordination with the anticipated certification of EHR

technology to obtain and meaningfully use CEHRT. We recognize that there may be additional costs that result from various discretionary policy choices by providers. However, those costs cannot be estimated as the potential for variance by provider type, organization size, place of service, geographic location, patient population, and the impact of state and local laws is extensive and such variations are not captured in this analysis.

E. Accounting Statement and Table

When a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the classification of the expenditures associated with the provisions of this final rule with comment period.

Monetary annualized benefits and non-budgetary costs are presented as discounted flows using 3 percent and 7 percent factors in the following tables. We are not able to explicitly define the universe of those additional costs, nor specify what the high or low range might be to implement EHR technology in this final rule with comment period. We note that federal annualized monetized transfers represent the net total of annual incentive payments in the Medicare and Medicaid EHR Incentive programs less the reductions in Medicare payments to providers failing to demonstrate meaningful use as a result of the related Medicare payment adjustments.

(1) EHR Incentive Programs in 2015 Through 2017

TABLE 41—ACCOUNTING STATEMENT FOR MODIFICATIONS: CLASSIFICATION OF ESTIMATED COST REDUCTIONS AND BENEFITS CYs 2015 THROUGH 2017
[in millions]

Category	Benefits				
		Low estimate	High estimate		
Annualized Monetized Cost Reductions to Private Industry Associated with Reporting Requirements	2015	\$52.8 \$52.8	\$68.9 \$68.9	7% 3%	CYs 2015–2017.
Qualitative—Other private industry and societal benefits associated with the reduction in provider reporting burden and with having additional time to meet the requirements of the program.					

In this final rule with comment period, there is no estimated increase in costs associated with incentive payments or payment adjustments for the Medicare and Medicaid EHR Programs attributable to the modifications to the program proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule.

(2) Stage 3

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities such as temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting. Transfers related to the payment of EHR Incentive

Payments for 2017 through 2020 based on the policies in this final rule with comment period and the estimated reduction in Medicare payments through the application of payment adjustments for the same period. We note that this estimate relates only to the policies in this final rule with comment period and does not address subsequent changes pertaining to the MIPS program as established by MACRA which will be further defined in future rulemaking.

TABLE 42—STAGE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYs 2017 THROUGH 2020
[in millions]

Category				
Benefits				
Qualitative	Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like.			
Costs				
	Year dollar	Estimates (in millions)	Unit discount rate	Period covered.
		Primary estimate		
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements.	2017	\$478.1 \$478.4	7% 3%	CY 2017.
Qualitative—Other private industry costs associated with the adoption of EHR technology.	These costs would include the impact of EHR activities such as reduced staff productivity related to learning how to use the EHR technology, the need for additional staff to work with HIT issues, and administrative costs related to reporting.			
Transfers				
	Year dollar	Estimates (in millions)	Unit discount rate	Period covered
Federal Annualized Monetized	2017	\$1,000.4 \$954.8	7% 3%	CYs 2017–2020.
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals.			

VI. Response to Comments

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

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare &

Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

§ 412.64 [Amended]

■ 2. Section 412.64 is amended by—

■ A. In paragraph (d)(4)(ii)(A) by removing the phrase “April 1” wherever it appears and adding the phrase “July 1” in its place.

■ B. In paragraph (d)(4)(ii)(B)(1) by removing the phrase “April 1” and adding the phrase “July 1” in its place.

■ C. In paragraph (d)(4)(ii)(B)(2) by removing the phrase “April 1” and adding the phrase “July 1” in its place.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 3. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 4. Section 495.4 is amended as follows:

■ A. Adding the definition of “API” in alphabetical order.

■ B. Revising the definition of “Certified electronic health record technology”.

■ C. Amending the definition of “EHR reporting period” by—

■ i. Redesignating paragraphs (1)(i), (1)(ii), (1)(iii) introductory text, (1)(iii)(A), (1)(iii)(B), (1)(iii)(C), (1)(iii)(D), and (1)(iv) as paragraphs (1)(i)(A), (1)(i)(B), (1)(i)(C) introductory text, (1)(i)(C)(1), (1)(i)(C)(2), (1)(i)(C)(3), (1)(i)(C)(4), and (1)(i)(D), respectively.

■ ii. Adding new paragraph (1)(i) introductory text.

■ iii. Adding new paragraphs (1)(ii) and (iii).

■ iv. Redesignating paragraphs (2)(i), (2)(ii), (2)(iii) introductory text, (2)(iii)(A), (2)(iii)(B), (2)(iii)(C), and

(2)(iii)(D), as paragraphs (2)(i)(A), (2)(i)(B), (2)(i)(C) introductory text and (2)(i)(C)(1), (2)(i)(C)(2), (2)(i)(C)(3), and (2)(i)(C)(4), respectively.

■ v. Adding new paragraphs (2)(i) introductory text.

■ vi. Adding new paragraphs (2)(ii) and (iii).

■ D. Amending the definition of “EHR reporting period for a payment adjustment year” by:

■ i. Redesignating paragraphs (1)(i)(A), (1)(i)(B), (1)(ii), (1)(iii)(A), and (1)(iii)(B) as paragraphs (1)(i)(A)(1), (1)(i)(A)(2), (1)(i)(B), (1)(i)(C)(1) and (1)(i)(C)(2), respectively.

■ ii. In newly redesignated paragraph (1)(i)(A)(1), by removing the cross-reference “paragraphs (1)(i)(B), (ii), and (iii)” and adding in its place the cross-reference “paragraphs (1)(i)(A)(2), (1)(i)(B), and (1)(i)(C)”.

■ iii. In newly redesignated paragraph (1)(i)(A)(2), by removing the cross-reference “paragraphs (1)(iii) or (1)(iv)” and adding in its place the cross-reference “paragraph (1)(i)(C)”.

■ iv. Adding new paragraph (1)(i) introductory text.

■ v. Adding new paragraph. (1)(ii).

■ vi. Redesignating paragraphs (2)(i)(A), (2)(i)(B), (2)(ii), (2)(iii)(A), and (2)(iii)(B) as paragraphs (2)(i)(A)(1), (2)(i)(A)(2), (2)(i)(B), (2)(i)(C)(1), and (2)(i)(C)(2), respectively.

■ vii. In newly redesignated paragraph (2)(i)(A)(1), by removing the cross-reference “paragraphs (2)(i)(B), (ii), and (iii)” and adding in its place the cross-reference “paragraphs (2)(i)(A)(2), (2)(i)(B), and (2)(i)(C)”.

■ viii. In newly redesignated paragraph (2)(i)(A)(2), by removing the cross-reference “paragraph (2)(iii)” and adding in its place the cross-reference “paragraph (2)(i)(C)”.

■ ix. Adding new paragraph (2)(i) introductory text.

■ x. Adding new paragraphs (2)(ii) and (iii).

■ xi. Redesignating paragraphs (3)(i) and (3)(ii) as paragraphs (3)(i)(A) and (3)(i)(B).

■ xii. In newly redesignated paragraph (3)(i)(A), by removing the cross-reference “paragraph (3)(ii)” and adding in its place the cross-reference “paragraph (3)(i)(B)”.

■ xiii. Adding new paragraph (3)(i) introductory text.

■ xiv. Adding new paragraphs (3)(ii) and (iii).

■ e. Amend the definition of “Meaningful EHR user” by:

■ i. In paragraph (1), by removing the reference “§ 495.8” and adding in its place the reference “§ 495.40”.

■ ii. In paragraph (1), by removing the reference “under § 495.6 ” and adding

in its place the reference “under §§ 495.20, 495.22, and 495.24”.

The additions and revision read as follows:

§ 495.4 Definitions.

* * * * *

API stands for application programming interface.

Certified electronic health record technology (CEHRT) means the following:

(1) For any Federal fiscal year or calendar year before 2018, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets one of the following:

(i) The 2014 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the certification criteria that are necessary to be a Meaningful EHR User (as defined in this section), including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(ii) Certification to—

(A) The following certification criteria:

(1) CPOE at—

(i) 45 CFR 170.314(a)(1), (18), (19) or (20); or

(ii) 45 CFR 170.315(a)(1), (2) or (3).

(2)(i) Record demographics at 45 CFR 170.314(a)(3); or

(ii) 45 CFR 170.315(a)(5).

(3)(i) Problem list at 45 CFR

170.314(a)(5); or

(ii) 45 CFR 170.315(a)(6).

(4)(i) Medication list at 45 CFR

170.314(a)(6); or

(ii) 45 CFR 170.315(a)(7).

(5)(i) Medication allergy list 45 CFR 170.314(a)(7); or

(ii) 45 CFR 170.315(a)(8).

(6)(i) Clinical decision support at 45 CFR 170.314(a)(8); or

(ii) 45 CFR 170.315(a)(9).

(7) Health information exchange at transitions of care at one of the following:

(i) 45 CFR 170.314(b)(1) and (2).

(ii) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).

(iii) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).

(iv) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).

(v) 45 CFR 170.314(b)(8) and (h)(1).

(vi) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).

(vii) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).

(viii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).

(ix) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).

(x) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).

(xi) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).

(xii) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).

(xiii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).

(xiv) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).

(xv) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).

(xvi) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).

(xvii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).

(xviii) 45 CFR 170.314(h)(1) and 170.315(b)(1).

(xix) 45 CFR 170.315(b)(1) and (h)(1).

(xx) 45 CFR 170.315(b)(1) and (h)(2).

(xxi) 45 CFR 170.315(b)(1), (h)(1), and (h)(2); and

(B) Clinical quality measures at—

(1) 45 CFR 170.314(c)(1) or 170.315(c)(1);

(2) 45 CFR 170.314(c)(2) or 170.315(c)(2);

(3) 45 CFR 170.314(c)(3) or 170.315(c)(3); and

(C) Privacy and security at—

(1) 45 CFR 170.314(d)(1) or 170.315(d)(1);

(2) 45 CFR 170.314(d)(2) or 170.315(d)(2);

(3) 45 CFR 170.314(d)(3) or 170.315(d)(3);

(4) 45 CFR 170.314(d)(4) or 170.315(d)(4);

(5) 45 CFR 170.314(d)(5) or 170.315(d)(5);

(6) 45 CFR 170.314(d)(6) or 170.315(d)(6);

(7) 45 CFR 170.314(d)(7) or 170.315(d)(7);

(8) 45 CFR 170.314(d)(8) or 170.315(d)(8); and

(D) The certification criteria that are necessary to be a Meaningful EHR User (as defined in this section), including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(iii) The definition for 2018 subsequent years specified in paragraph (2) of this definition.

(2) For 2018 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria—

(i) The definition for 2018 subsequent years specified in paragraph (2) of this definition.

(2) For 2018 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria—

(i) At 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) The applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (3).

* * * * *
EHR reporting period. * * *

(1) * * *
(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) For the CY 2015 payment year, any continuous 90-day period within CY 2015.

(B) For the CY 2016 payment year:

(1) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2016.

(2) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, the CY 2016.

(C) For the CY 2017 payment year under the Medicaid EHR Incentive Program:

(1) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2017.

(2) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, the CY 2017.

(3) For the EP demonstrating the Stage 3 objectives and measures at § 495.24, any continuous 90-day period within CY 2017.

(iii) The following are applicable beginning with the CY 2018 payment year under the Medicaid EHR Incentive Program:

(A) For the payment year in which the EP is first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(2) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) For the FY 2015 payment year, any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015.

(B) For the FY 2016 payment year as follows:

(1) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2016.

(2) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, the CY 2016.

(C) For the FY 2017 payment year under the Medicaid EHR Incentive Program:

(1) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2017.

(2) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, the CY 2017.

(3) For the eligible hospital or CAH demonstrating the Stage 3 objectives and measures at § 495.24, any continuous 90-day period within CY 2017.

(iii) The following are applicable beginning with the FY 2018 payment year under the Medicaid EHR Incentive Program:

(A) For the payment year in which the eligible hospital or CAH is first demonstrating it is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the eligible hospital or CAH first successfully demonstrates it is a meaningful EHR user, the calendar year.

EHR reporting period for a payment adjustment year. * * *

(1) * * *
(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) In 2015 as follows:

(1) If an EP has not successfully demonstrated he or she is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2015 and applies for the CY 2016 and 2017 payment adjustment years.

(2) If in a prior year an EP has successfully demonstrated he or she is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2015 and applies for the CY 2017 payment adjustment year.

(B) In 2016 as follows:

(1) If an EP has not successfully demonstrated he or she is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the CY 2017 and 2018 payment adjustment years. For the CY 2017 payment adjustment year, the EHR reporting period must end before and the EP must successfully register for and attest to meaningful use no later than October 1, 2016.

(2) If in a prior year an EP has successfully demonstrated he or she is a meaningful EHR user, the EHR reporting period is CY 2016 and applies for the CY 2018 payment adjustment year.

(C) In 2017 as follows:

(1) If an EP has not successfully demonstrated he or she is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the CY 2018 payment adjustment year. For the CY 2018 payment adjustment year, the EHR reporting period must end before and the EP must successfully register for and attest to meaningful use no later than October 1, 2017.

(2) If an EP is demonstrating Stage 3 of meaningful use in 2017 under § 495.24 in the Medicaid program, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2019 payment adjustment year.

(2) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) In 2015 as follows:

(1) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015 and applies for the FY 2016 and 2017 payment adjustment years.

(2) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015 and applies for the FY 2017 payment adjustment year.

(B) In 2016 as follows:

(1) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous

90-day period within CY 2016 and 2017 applies for the FY 2017 and 2018 payment adjustment years. For the FY 2017 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2016.

(2) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2016 and applies for the FY 2018 payment adjustment year.

(C) In 2017 as follows:

(1) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2018 and 2019 payment adjustment years. For the FY 2018 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2017.

(2) If an eligible hospital is demonstrating Stage 3 of meaningful use under § 495.24, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2019 payment adjustment year.

(3) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2017 and applies for the FY 2019 payment adjustment year.

(iii) The following are applicable beginning in 2018:

(A) Except as provided in paragraph (2)(iii)(B) of this definition, the EHR reporting period is the calendar year that is 2 years before the payment adjustment year.

(B) If an eligible hospital is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, the EHR reporting period for that payment adjustment year is the same continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within the calendar year that is 2 years before that payment adjustment year.

(3) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) In 2015 as follows:

(1) The EHR reporting period is any continuous 90-day period within the

period beginning on October 1, 2014 and ending on December 31, 2015 and applies for the FY 2015 payment adjustment year.

(B) In 2016 as follows:

(1) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the FY 2016 payment adjustment year.

(2) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2016 and applies for the FY 2016 payment adjustment year.

(C) In 2017 as follows:

(1) If the CAH has not successfully demonstrated meaningful EHR use in a prior year the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2017 payment adjustment year.

(2) If a CAH is demonstrating Stage 3 of meaningful use under § 495.24, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for that begins on the first day of second quarter of the FY 2017 payment adjustment year.

(3) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2017 and applies for the FY 2017 payment adjustment year.

(iii) The following are applicable beginning in 2018:

(A) Except as provided in paragraph (3)(iii)(B) of this definition, the EHR reporting period is the calendar year that begins on the first day of second quarter of the Federal fiscal year that is the payment adjustment year.

(B) If a CAH is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year, then any continuous 90-day period within such calendar year. The EHR reporting period for that payment adjustment year is the same continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within the calendar year that that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year.

* * * * *

§ 495.6 [Redesignated as § 495.20]

■ 5. Redesignate § 495.6 as § 495.20.

§ 495.8 [Redesignated as § 495.40]

■ 6. Redesignate § 495.8 as § 495.40.

§ 495.10 [Redesignated as § 495.60]

■ 7. Redesignate § 495.10 as § 495.60.

■ 8. Newly redesignated § 495.20 is amended by revising the section heading and adding new introductory text to read as follows.

§ 495.20 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs before 2015.

The following criteria are applicable before 2015:

* * * * *

■ 9. Section § 495.22 is added to read as follows:

§ 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2017.

(a) *General rules.* (1) The criteria specified in this section are applicable for all EPs, eligible hospitals, and CAHs for 2015 through 2017.

(2) For 2017 only, EPs, eligible hospitals, and CAHs have the option to use the criteria specified for 2018 (as outlined at § 495.24) instead of the criteria specified in this section.

(b) *Criteria for EPs for 2015 through 2017—(1) General rule regarding criteria for meaningful use for 2015 through 2017 for EPs.* Except as specified in paragraph (b)(2) of this section, EPs must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for non-applicable objectives.* (i) An EP may exclude a particular objective contained in paragraph (e) of this section, if the EP meets all of the following requirements:

(A) Must ensure that the objective in paragraph (e) of this section includes an option for the EP to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation to the exclusion.

(C) Attests.

(ii) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section.

(c) *Criteria for eligible hospitals and CAHs for 2015 through 2017—(1) General rule regarding criteria for meaningful use for 2015 through 2017 for eligible hospitals and CAHs.* Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for non-applicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective contained in paragraph (e) of this section, if the eligible hospital or CAH meets all of the following requirements:

(A) Must ensure that the objective in paragraph (e) of this section includes an option for the eligible hospital or CAH to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation to the exclusion.

(C) Attests.

(ii) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section.

(d) *Many of the objectives and associated measures in paragraph (e) of this section rely on measures that count unique patients or actions.* (1) If a measure (or associated objective) in paragraph (e) of this section references paragraph (d) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data was entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (d) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(e) *Meaningful use objectives and measures for 2015 through 2017—(1) Protect patient health information—* (i) *Objective.* Protect electronic protected health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

(ii) *Measures—(A) EP measure.* Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.

(B) *Eligible hospital or CAH measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including Addressing the security (to include encryption) of ePHI created or maintained in CEHRT in

accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary, and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(2) *Clinical decision support—* (i) *Objective.* Use clinical decision support to improve performance on high-priority health conditions.

(ii) *EP measures—(A) Measure.* In order for EPs to meet the objective they must satisfy both of the following measures:

(1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

(2) Enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period may be excluded from the measure under paragraph (e)(2)(i)(A)(2) of this section.

(C) *Alternate specifications.* An EP previously scheduled to be in Stage 1 in 2015 may meet an alternate objective and measure specified in paragraph (e)(2)(ii)(C)(1) and (2) in place of the measure outlined under paragraph (e)(2)(ii)(A)(1) of this section for an EHR reporting period in 2015 only.

(1) *Alternate objective.* Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.

(2) *Alternate measure.* Implement one clinical decision support rule.

(iii) *Eligible hospital and CAH measures—(A) Measure.* In order for eligible hospitals and CAHs to meet the objective they must satisfy both of the following measures:

(1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

(2) Enabled and implemented the functionality for drug-drug and drug-

allergy interaction checks for the entire EHR reporting period.

(B) *Alternate specifications.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may meet an alternate measure described in paragraph (e)(2)(iii)(B)(2) of this section in place of the measure described in paragraph (e)(2)(iii)(A)(1) of this section for an EHR reporting period in 2015.

(1) *Alternate objective.* Implement one clinical decision support rule relevant to a high priority hospital condition along with the ability to track compliance with that rule.

(2) *Alternate measure.* Implement one clinical decision support rule.

(3) *Computerized provider order entry.* (i) *Objective.* Use computerized provider order entry 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.

(ii) *EP measures.* (A) *Measures.* An EP must meet the following 3 measures, subject to paragraph (d) of this section:

(1) More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(2) More than 30 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(3) More than 30 percent of radiology orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* (1) For the measure specified in paragraph (e)(3)(ii)(A)(1) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(2) For the measure specified in paragraph (e)(3)(ii)(A)(2) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(3) For the measure specified in paragraph (e)(3)(ii)(A)(3) of this section, any EP who writes fewer than 100 radiology orders during the EHR reporting period.

(C) *Alternate exclusions and specifications.* An EP previously scheduled to be in Stage 1 in 2015 may meet an alternate measure (e)(3)(ii)(C)(1) in place of the measure outlined under paragraph (e)(3)(ii)(A)(1) of this section, and may exclude the measures outlined under paragraphs (e)(3)(ii)(A)(2) and (3) of this section for an EHR reporting period in 2015. An EP previously scheduled to be in Stage 1 in 2016 may exclude the measures outlined under

paragraphs (e)(3)(ii)(A)(2) and (3) of this section for an EHR reporting period in 2016.

(1) *Alternate measure 1 in 2015.*

Subject to paragraph (d) of this section—

(i) More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP during the EHR reporting period have at least one medication order entered using CPOE; or

(ii) More than 30 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(2) *Alternate exclusions in 2015.* An EP scheduled to be in Stage 1 in 2015 may exclude the measures specified in paragraphs (e)(3)(ii)(A)(2) and (e)(3)(ii)(A)(3) of this section in 2015.

(3) *Alternate exclusions in 2016.* An EP scheduled to be in Stage 1 in 2016 may exclude the measure specified in paragraph (e)(3)(ii)(A)(3) of this section in 2016.

(iii) *Eligible hospital and CAH measures.* (A) An eligible hospital or CAH must meet the following 3 measures, subject to paragraph (d) of this section:

(1) More than 60 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(2) More than 30 percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(3) More than 30 percent of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(B) *Alternate exclusions and specifications.* (1) An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may meet an alternate measure specified in paragraph (e)(3)(iii)(B)(2) of this section in place of the measure outlined under paragraph (e)(3)(iii)(A)(1) of this section, and may exclude the measures outlined under paragraphs (e)(3)(iii)(A)(2) and (e)(3)(iii)(A)(3) of this section for an EHR reporting period in 2015. An eligible hospital or CAH previously scheduled to be in Stage 1 in 2016 may exclude the measures outlined under paragraphs (e)(3)(iii)(A)(2) and (3) of

this section for an EHR reporting period in 2016.

(2) *Alternate measure 1 in 2015.*

Subject to paragraph (d) of this section—

(i) More than 30 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE; or

(ii) More than 30 percent of medication orders created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(3) *Alternate exclusions in 2015 and 2016.* An eligible hospital or CAH scheduled to be in Stage 1 in 2015 may exclude the following measures in 2015 and eligible hospital or CAH scheduled to be in Stage 1 in 2016 may exclude the following measures in 2016:

(i) The measure specified in paragraph (e)(3)(iii)(A)(2) of this section.

(ii) The measure specified in paragraph (e)(3)(iii)(A)(3) of this section.

(4) *Electronic prescribing—(i) Objective.* For EPs, generate and transmit permissible prescriptions electronically (eRx); and, for eligible hospitals and CAHs, generate, and transmit permissible discharge prescriptions electronically (eRx).

(ii) *EP measure—(A) Measure.* Subject to paragraph (d) of this section, more than 50 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who—

(1) Writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(2) Does not have a pharmacy within his or her organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.

(C) *Alternate specification.* In 2015 an EP—

(1) Previously scheduled to be in Stage 1 in 2015 may meet an alternate measure under paragraph (e)(4)(ii)(C)(2) of this section in place of the measure outlined under paragraph (e)(4)(ii)(A) of this section; and

(2) Subject to paragraph (d) of this section, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.

(iii) *Eligible hospital and CAH measure—(A) Measure.* Subject to paragraph (d) of this section, more than 10 percent of hospital discharge medication orders for permissible prescriptions are queried for a drug formulary and transmitted electronically using CEHRT.

(B) *Exclusion in accordance with paragraph (c)(2) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

(C) *Alternate exclusions.* (1) An eligible hospital or CAH previously scheduled to be in—

(i) Stage 1 in 2015 may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2015; or

(ii) Stage 2 in 2015 may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2015.

(2) An eligible hospital or CAH previously scheduled to be in—

(i) Stage 1 in 2016, may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2016; or

(ii) Stage 2 in 2016, may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2016.

(5) *Health Information Exchange—(i) Objective.* The EP, eligible hospital or CAH who transitions a patient to another setting of care or provider of care or refers a patient to another provider of care provides a summary care record for each transition of care or referral.

(ii) *EP measure.* (A) *Measure.* Subject to paragraph (d) of this section, the EP who transitions or refers his or her patient to another setting of care or provider of care must do the following:

(1) Use CEHRT to create a summary of care record.

(2) Electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period.

(C) *Alternate exclusion.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(5)(ii)(A) of this section for an EHR reporting period in 2015.

(iii) *Eligible hospital and CAH measure—(A) Measure.* Subject to paragraph (d) of this section, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care must do the following:

(1) Use CEHRT to create a summary of care record.

(2) Electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

(B) *Alternate exclusion.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(5)(iii)(A) of this section for an EHR reporting period in 2015.

(6) *Patient specific education—(i) Objective.* Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.

(ii) *EP measure—(A) Measure.* Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(C) *Alternate exclusion.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(6)(ii)(A) of this section for an EHR reporting period in 2015.

(iii) *Eligible hospital and CAH measure—(A) Measure.* More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources identified by CEHRT.

(B) *Alternate exclusion.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(6)(iii)(A) of this section for an EHR reporting period in 2015.

(7) *Medication reconciliation—(i) Objective.* The EP, eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant performs medication reconciliation.

(ii) *EP measure—(A) Measure.* Subject to paragraph (d) of this section, the EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who was not the recipient of any

transitions of care during the EHR reporting period.

(C) *Alternate exclusion.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(7)(ii)(A) of this section for an EHR reporting period in 2015.

(iii) *Eligible hospital or CAH measure.* An eligible hospital or CAH must meet the following measure, subject to paragraph (d) of this section:

(A) *Measure.* Subject to paragraph (d) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(B) *Alternate exclusion.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(7)(iii)(A) of this section for an EHR reporting period in 2015.

(8) *Patient electronic access—(i) EP objective.* Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

(A) *EP measures.* An EP must meet the following 2 measures:

(1) *Measure 1:* More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download and transmit to a third party their health information subject to the EP's discretion to withhold certain information.

(2) *Measure 2:* For an EHR reporting period—

(i) In 2015 and 2016, at least 1 patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits his or her health information to a third party during the EHR reporting period.

(ii) In 2017, more than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads or transmits their health information to a third party during the EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section—(1)* Any EP who neither orders nor creates any of the information listed for inclusion as part of the measure in paragraph (e)(8)(ii)(A)(1) or (2) of this section, except for "Patient name" and "Provider's name and office contact information," is excluded from paragraphs (e)(8)(ii)(A)(1) and (2) of this section.

(2) Any EP who conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the Federal Communications Commission on the first day of the EHR reporting period is excluded from paragraph (e)(8)(ii)(A)(2) of this section.

(C) *Alternate exclusion.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(8)(ii)(A)(2) of this section for an EHR reporting period in 2015.

(ii) *Eligible hospital and CAH objective.* Provide patients the ability to view online, download, and transmit information within 36 hours of hospital discharge.

(A) *Eligible hospital and CAH measures.* An eligible hospital or CAH must meet the following 2 measures:

(1) *Measure 1.* More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have timely access to view online, download and transmit to a third party their health information.

(2) *Measure 2.* For an EHR reporting period—

(i) In 2015 or 2016, at least 1 patient (or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her information during the EHR reporting period; and

(ii) In 2017, more than 5 percent of unique patients (or patient-authorized representatives) discharged from the inpatient or emergency department (POS 21 or POS 23) of an eligible hospital or CAH during the EHR reporting period view, download or transmit to a third party their health information during the EHR reporting period.

(B) *Exclusion applicable under paragraph (c)(2) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (e)(8)(iii)(A)(2) of this section.

(C) *Alternate exclusion.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph

(e)(8)(iii)(A)(2) of this section for an EHR reporting period in 2015.

(9) *Secure messaging*—(i) *EP objective*. Use secure electronic messaging to communicate with patients on relevant health information.

(ii) *EP measure*—(A) *Measure*. For an EHR reporting period—

(1) In 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled during the EHR reporting period;

(2) In 2016, for at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period; and

(3) In 2017, for more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section*. An EP may exclude from the measure if he or she—

(1) Has no office visits during the EHR reporting period; or

(2) Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the Federal Communications Commission on the first day of the EP's EHR reporting period.

(C) *Alternate specification*. An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(9)(ii)(A) of this section for an EHR reporting period in 2015.

(10) *Public Health Reporting*—(i) *EP Public Health Reporting*—(A) *Objective*. The EP is in active engagement with a public health agency to submit electronic public health data from CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures*. In order to meet the objective under paragraph (e)(10)(i)(A) of this section, an EP must choose from measures 1 through 3 (as specified in paragraphs (e)(10)(i)(B)(1) through (3) of this section) and must successfully attest to any combination of two measures. The EP may attest to measure 3 (as specified in paragraph

(e)(10)(i)(B)(3) of this section more than one time. These measures may be met by any combination in accordance with applicable law and practice.

(1) *Immunization registry reporting*. The EP is in active engagement with a public health agency to submit immunization data.

(2) *Syndromic surveillance reporting*. The EP is in active engagement with a public health agency to submit syndromic surveillance data.

(3) *Specialized registry reporting*. The EP is in active engagement to submit data to specialized registry.

(C) *Exclusions in accordance with paragraph (b)(2) of this section*. (1) Any EP meeting one or more of the following criteria may be excluded from the immunization registry reporting measure in paragraph (e)(10)(i)(B)(1) of this section if the EP:

(i) Does not administer any immunizations to any of the populations for which data is collected by his or her jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of his or her EHR reporting period.

(iii) Operates in a jurisdiction in which no immunization registry or immunization information system has declared readiness to receive immunization data from the EP at the start of the EHR reporting period.

(2) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (e)(10)(i)(B)(2) of the section if the EP:

(i) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system;

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

(3) Any EP who meets one or more of the following criteria may be excluded from the specialized registry reporting measure described in paragraph (e)(10)(i)(B)(3) of this section if the EP:

(i) Does not diagnose or treat any disease or condition associated with or collect relevant data that is required by a specialized registry in their jurisdiction during the EHR reporting period;

(ii) Operates in a jurisdiction for which no specialized registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

(iii) Operates in a jurisdiction where no specialized registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(D) *Alternate specifications*. An EP previously scheduled to be in Stage 1 in 2015 may choose from measures 1 through 3 (as specified in paragraphs (e)(10)(i)(B)(1) through (3) of this section) and must successfully attest to any one measure in accordance with applicable law and practice for an EHR reporting period in 2015.

(ii) *Eligible hospital and CAH Public Health and Clinical Data Registry reporting objective*. (A) *Objective*. The eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures*. In order to meet the objective under paragraph (e)(10)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 4 (as described in paragraphs (e)(10)(ii)(B)(1) through (4) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting the measure specified in paragraph (e)(10)(ii)(B)(3) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit immunization.

(2) *Syndromic surveillance reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data

(3) *Specialized registry reporting*. The eligible hospital or CAH is in active engagement to submit data to a specialized registry.

(4) *Electronic reportable laboratory result reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (c)(2) of this section.* (1) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure specified in paragraph (e)(10)(ii)(B)(1) of this section if the eligible hospital or CAH:

(i) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the eligible hospital or CAH at the start of the EHR reporting period.

(2) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (e)(10)(ii)(B)(2) of this section if the eligible hospital or CAH:

(i) Does not have an emergency or urgent care department.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

(3) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the specialized registry reporting measure described in paragraph (e)(10)(i)(B)(3) of this section if the EP:

(i) Does not diagnose or directly treat any disease associated with or collect relevant data is required by a specialized registry for which the eligible hospital or CAH is eligible in their jurisdiction.

(ii) Operates in a jurisdiction for which no specialized registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition

at the start of the EHR reporting period; or

(iii) Operates in a jurisdiction where no specialized registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(4) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (d)(10)(ii)(B)(4) of this section if the eligible hospital or CAH:

(i) Does not perform or order laboratory tests that are reportable in the eligible hospital's or CAH's jurisdiction during the EHR reporting period

(ii) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from eligible hospitals or CAHs at the start of the EHR reporting period.

(D) *Alternate specification.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may choose from measures 1 through 4 (as specified in paragraphs (e)(10)(ii)(B)(1) through (4) of this section) and must successfully attest to any 2 measures. These measures may be met by any combination, including meeting the measures specified in paragraph (e)(10)(ii)(B)(3) of this section multiple times, in accordance with applicable law and practice.

■ 10. Section 495.24 is added to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2018 and subsequent years.

The following criteria are optional for EPs, eligible hospitals, and CAHs in 2017 as outlined at § 495.40(a)(2)(i)(E)(3) and (b)(2)(E)(3) and applicable for all EPs, eligible hospitals, and CAHs for 2018 and subsequent years:

(a) *Stage 3 criteria for EPs—(1) General rule regarding Stage 3 criteria for meaningful use for EPs.* Except as specified in paragraphs (a)(2) through (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An EP may meet the criteria for

2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the EP meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective

(3) *Exclusion for non-applicable objectives and measures.* (i) An EP may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the EP meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An EP may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (a)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement or upgrade its CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(b) *Stage 3 criteria for eligible hospitals and CAHs—(1) General rule regarding Stage 3 criteria for meaningful use for eligible hospitals or CAHs.*

Except as specified in paragraphs (b)(2) and (3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An eligible hospital or CAH may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the eligible hospital or CAH meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) *Exclusion for non-applicable objectives and measures.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the eligible hospital or CAH meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An eligible hospital or CAH may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (b)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) *Exception for Medicaid eligible hospitals or CAHs that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals or CAHs who adopt, implement or upgrade CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(c) *Objectives and associated measures in paragraph (d) of this section that rely on measures that count unique patients or actions.* (1) If a measure (or associated objective) in paragraph (d) of this section references paragraph (c) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data was entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (c) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(d) *Stage 3 objectives and measures for EPs, eligible hospitals, and CAHs—*

(1) *Protect patient health information—*

(i) *EP protect patient health information.* (A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(ii) *Eligible hospital/CAH protect patient health information—*(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. (2) *Electronic prescribing—*(i) *EP electronic prescribing—*(A) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (c) of this section, more than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (1) Any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(2) Any EP who does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period.

(ii) *Eligible hospital/CAH electronic prescribing—*(A) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (c) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period.

(3) *Clinical decision support—*(i) *EP clinical decision support—*(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.* (1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(C) *Exclusion in accordance with paragraph (a)(3) of this section for paragraph (d)(3)(i)(B)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period.

(ii) *Eligible hospital/CAH clinical decision support—*(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.* (1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(4) *Computerized provider order entry (CPOE)—*(i) *EP CPOE—*(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare

professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures*. Subject to paragraph (c) of this section—

(1) More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(2) More than 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

(3) More than 60 percent of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section*. (1) For the measure specified in paragraph (d)(4)(i)(B)(1) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(2) For the measure specified in paragraph (d)(4)(i)(B)(2) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(3) For the measure specified in paragraph (d)(4)(i)(B)(3) of this section, any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

(ii) *Eligible hospital and CAH CPOE—(A) Objective*. Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures*. Subject to paragraph (c) of this section—

(1) More than 60 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

(2) More than 60 percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

(3) More than 60 percent of diagnostic imaging orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(5) *Patient electronic access to health information—(i) EP patient electronic access to health information—(A) Objective*. The EP provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) *Measures*. EPs must meet the following two measures:

(1) For more than 80 percent of all unique patients seen by the EP—

(i) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(ii) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(2) The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section*. (1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1) and (B)(2) of this section.

(2) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1) and (2) of this section.

(ii) *Eligible hospital and CAH patient electronic access to health information—(A) Objective*. The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) *Measures*. Eligible hospitals and CAHs must meet the following two measures:

(1) For more than 80 percent of all unique patients seen by the EP or

discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(i) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(ii) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(2) The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusion in accordance with paragraph (b)(3) of this section*. Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (d)(5)(i)(B)(1) and (2) of this section.

(6) *Coordination of care through patient engagement—(i) EP coordination of care through patient engagement—(A) Objective*. Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) *Measures*. In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(6)(i)(B)(1), (2), and (3) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(1) During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and either of the following:

(i) View, download or transmit to a third party their health information;

(ii) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(iii) A combination of paragraphs (d)(6)(i)(B)(1)(i) and (ii).

(iv) For an EHR reporting period in 2017 only, an EP may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(i)(B)(1) of this section.

(2) During the EHR reporting period—

(i) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient; or

(ii) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(3) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* (1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1), (2), and (3) of this section.

(2) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1), (2), and (3) of this section.

(ii) *Eligible hospital and CAH coordination of care through patient engagement—(A) Objective.* Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraph (d)(6)(ii)(B)(1), (2), and (3) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(1) During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic

health record made accessible by the provider and one of the following:

(i) View, download or transmit to a third party their health information.

(ii) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT.

(iii) A combination of paragraphs (d)(6)(ii)(B)(1)(i) and (ii).

(iv) For an EHR reporting period in 2017, an eligible hospital or CAH may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(ii)(B)(1) of this section.

(2) During the EHR reporting period—

(i) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(ii) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(3) Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusions under paragraph (b)(3) of this section.* Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(ii)(B)(1), (B)(2), and (B)(3) of this section.

(7) *Health information exchange—(i) EP health information exchange—(A) Objective.* The EP provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient,

and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(7)(i)(B)(1), (2), and (3), in order to meet the objective. Subject to paragraph (c) of this section—

(1) *Measure 1.* For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document.

(3) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for two of the following three clinical information sets:

(i) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) *Medication allergy.* Review of the patient's known allergic medications.

(iii) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* An EP must be excluded when any of the following occur:

(1) Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period must be excluded from paragraph (d)(7)(i)(B)(1) of this section.

(2) Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(2) and (d)(7)(i)(B)(3) of this section.

(3) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units

with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(i)(B)(1) and (2) of this section.

(ii) *Eligible hospitals and CAHs health information exchange—(A) Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must attest to all three measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(7)(ii)(B)(1), (2), and (3). Subject to paragraph (c) of this section—

(1) *Measure 1.* For more than 50 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(3) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for two of the following three clinical information sets:

(i) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) *Medication allergy.* Review of the patient's known allergic medications.

(iii) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* (1) Any eligible hospital or CAH for whom the total of transitions or referrals received

and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(2) and (3) of this section.

(2) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(ii)(B)(1), and (2) of this section.

(8) *Public Health and Clinical Data Registry Reporting—(i) EP Public Health and Clinical Data Registry: Reporting objective—(A) Objective.* The EP is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(i)(A) of this section, an EP must choose from measures 1 through 5 (paragraphs (d)(8)(i)(B)(1) through (d)(8)(i)(B)(5) of this section) and must successfully attest to any combination of two measures. These measures may be met by any combination, including meeting measure specified in paragraph (d)(8)(i)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting:* The EP is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting

(3) *Electronic case reporting.* The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting.* The EP is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting.* The EP is in active engagement to submit data to a clinical data registry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(1) Any EP meeting one or more of the following criteria may be excluded from the immunization registry reporting

measure in paragraph (d)(8)(i)(B)(1) of this section if the EP:

(i) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of its EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(2) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (d)(8)(i)(B)(2) of the section if the EP:

(i) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs as of 6 months prior to the start of the EHR reporting period.

(3) Any EP meeting one or more of the following criteria may be excluded from the case reporting measure at paragraph (d)(8)(i)(B)(3) of this section if the EP:

(i) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(4) Any EP meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(i)(B)(4) of this section if the EP:

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in the EP's jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(5) Any EP meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(i)(B)(5) of this section if the EP:

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(ii) *Eligible hospital and CAH Public Health and Clinical Data Registry: Reporting objective*—(A) *Objective*. The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures*. In order to meet the objective under paragraph (d)(8)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (d)(8)(ii)(B)(1) through (6) of this section) and must successfully attest to any combination of four measures. These measures may be met by any combination, including meeting the measure specified in paragraph (d)(8)(ii)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and

receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(3) *Case reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting*. The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(6) *Electronic reportable laboratory result reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (b)(3) of this section*. (1) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure specified in paragraph (d)(8)(ii)(B)(1) of this section if the eligible hospital or CAH:

(i) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(2) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (d)(8)(ii)(B)(2) of this section if the eligible hospital or CAH:

(i) Does not have an emergency or urgent care department.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the

CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(3) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (d)(8)(ii)(B)(3) of this section if the eligible hospital or CAH:

(i) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(4) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(ii)(B)(4) of this section if the eligible hospital or CAH:

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(5) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(ii)(B)(5) of this section if the eligible hospital or CAH:

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(6) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (d)(8)(ii)(B)(6) of this section if the eligible hospital or CAH:

(i) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

■ 11. Newly redesignated § 495.40 is amended by:
■ a. In paragraph (a) introductory text, by removing the cross-reference “under § 495.6 of this subpart” and adding in its place the cross-reference “under § 495.20 or § 495.24”.

■ b. In paragraph (a)(1)(i)(B), by removing the cross-reference “under § 495.6(d) and § 495.6(e) of this subpart” and adding in its place the cross-reference “under § 495.20 or § 495.24”.

■ c. In paragraph (a)(1)(iii), by removing the cross-reference “in § 495.6 and § 495.8 of this subpart” and adding in its place the cross-reference “in § 495.20 or § 495.24 and § 495.40”.

■ d. Revising paragraph (a)(2)(i)(B).

■ e. In paragraph (a)(2)(i)(D) by removing the cross-reference “under § 495.6(a)(4) or (h)(3)” and adding in its place the cross-reference “in § 495.20(a)(4) or (h)(3)”.

■ f. Adding paragraphs (a)(2)(i)(E) and (F).

■ g. In paragraph (a)(2)(iv), by removing the cross-reference “in § 495.6 and § 495.8 of this subpart” and adding in its place the cross-reference “in § 495.20 or § 495.24 and § 495.40”.

■ h. In paragraph (b)(1)(i)(B), by removing the cross-reference “under

§ 495.6(f) and § 495.6(g)” and adding in its place the cross-reference “under § 495.20 or § 495.24”.

■ i. Redesignating paragraph (b)(1)(iv) as paragraph (b)(1)(iii).

j. In newly redesignated paragraph (b)(1)(iii), by removing the cross-reference “in § 495.6 and § 495.8 of this subpart” and adding in its place the cross-reference “in § 495.20 or § 495.24 and § 495.40”.

■ k. Revising paragraph (b)(2)(i)(B).

■ l. In paragraph (b)(2)(i)(D) by removing the cross-reference “under § 495.6(b)(4) or (i)(3)” and adding in its place the cross-reference “in § 495.20(b)(4) or (h)(3)”.

■ m. Adding paragraphs (b)(2)(i)(E), (F), and (G).

The revisions and additions read as follows:

§ 495.40 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(B) For calendar years before 2015, satisfied the required objectives and associated measures under § 495.20 for the EP’s stage of meaningful use.

* * * * *

(E) For CYs 2015 through 2017, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017 only, an EP may satisfy either of the following objectives and measures for meaningful use:

(1) Objectives and measures specified in § 495.22 (e); or

(2) Objectives and measures specified in § 495.24 (d).

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) For fiscal years before 2015, satisfied the required objectives and associated measures under § 495.20 for the eligible hospital or CAH’s stage of meaningful use.

* * * * *

(E) For CYs 2015 through 2017, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017 only, an eligible hospital or CAH may satisfy either of the following objectives and measures for meaningful use:

(1) Objectives and measures specified at § 495.22(e); or

(2) Objectives and measures specified at § 495.24(d).

(G) For CY 2018 and subsequent years, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.

* * * * *

§ 495.310 [Amended]

■ 12. Section 495.310(d) is amended by removing the reference “§ 495.10 of this part” and adding in its place the reference “§ 495.60”.

■ 13. Section 495.316 is amended by:

■ a. Revising paragraph (c) introductory text.

■ b. In paragraphs (d)(1)(i) and (iii) removing the phrase “The number, type, and practice location(s) of providers” and adding in its place “The number and type of providers”.

■ c. Adding paragraphs (d)(2)(iii), (f), (g), and (h) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(c) Subject to § 495.332 and § 495.352, the State is required to submit to CMS annual reports, in the manner prescribed by CMS, on the following:

* * * * *

(d) * * *

(2) * * *

(iii) Subject to § 495.332, the State may propose a revised definition for Stage 3 of meaningful use of CEHRT, subject to CMS prior approval, but only with respect to the public health and clinical data registry reporting objective described in § 495.24(d)(8).

* * * * *

(f) Each State must submit to CMS the annual report described in paragraph (c) of this section within 60 days of the end of the second quarter of the Federal fiscal year.

(g) The State must, on a quarterly basis and in the manner prescribed by CMS, submit a report(s) on the following:

(1) The State and payment year to which the quarterly report pertains.

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each EP and eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013.

(h)(1) Subject to paragraph (h)(2) of this section, the quarterly report described in paragraph (g) of this section must include the following for each EP and eligible hospital:

(i) The payment year number.

(ii) The provider’s National Provider Identifier or CCN, as appropriate.

(iii) Attestation submission date.

(iv) The state qualification.

(v) The state qualification date, which is the beginning date of the provider’s EHR reporting period for which it demonstrated meaningful use.

(vi) The State disqualification, if applicable.

(vii) The State disqualification date, which is the beginning date of the provider's EHR reporting period to which the provider attested but for which it did not demonstrate meaningful use, if applicable.

(2) The quarterly report described in paragraph (g) of this section is not required to include information on EPs who are eligible for the Medicaid EHR incentive program on the basis of being a nurse practitioner, certified nurse-midwife or physician assistant.

14. Section 495.352 is revised to read as follows:

§ 495.352 Reporting requirements.

(a) Beginning with the first quarter of calendar year 2016, each State must submit to HHS on a quarterly basis a

progress report, in the manner prescribed by HHS, documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

(b) The quarterly progress reports must include, but need not be limited to providing, updates on the following:

(1) State system implementation dates.

(2) Provider outreach.

(3) Auditing.

(4) State-specific State Medicaid HIT Plan tasks.

(5) State staffing levels and changes.

(6) The number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented or upgraded CEHRT and the amounts of incentive payments.

(7) The number and type of providers that qualified for an incentive payment on the basis of having demonstrated that they are meaningful users of CEHRT and the amounts of incentive payments.

(c) States must submit the quarterly progress reports described in this section within 30 days after the end of each federal fiscal year quarter.

Dated: September 23, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: September 25, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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Part IV

Department of Labor

Employment and Training Administration

20 CFR Part 655

Temporary Agricultural Employment of H-2A Foreign Workers in the Herding or Production of Livestock on the Range in the United States; Final Rule

DEPARTMENT OF LABOR**Employment and Training
Administration****20 CFR Part 655**

RIN 1205-AB70

**Temporary Agricultural Employment of
H-2A Foreign Workers in the Herding
or Production of Livestock on the
Range in the United States****AGENCY:** Employment and Training
Administration, Labor.**ACTION:** Final rule.

SUMMARY: The Department of Labor is issuing regulations to govern its certification of the employment of nonimmigrant workers in temporary or seasonal agricultural employment under the H-2A program. Specifically, these regulations establish standards and procedures for employers seeking to hire foreign temporary agricultural workers for job opportunities in herding and production of livestock on the range. These regulations are consistent with the Secretary of Labor's statutory responsibility to certify that there are not sufficient able, willing, qualified and available U.S. workers to perform these jobs, and that the employment of foreign workers will not adversely affect the wages and working conditions of workers in the United States similarly employed. Among the issues addressed in these regulations are the qualifying criteria for employing foreign workers in the applicable job opportunities, preparing job orders, program obligations of employers, filing of H-2A applications requesting temporary labor certification for range occupations, recruiting U.S. workers, determining the minimum offered wage rate, and the minimum standards for housing used on the range. The regulations establish a single set of standards and procedures applicable to employers seeking to hire foreign temporary agricultural workers for sheep and goat herding and range production of livestock, given the unique characteristics of these job opportunities in their industry.

DATES: *Effective Date:* This rule will be effective on November 16, 2015.**FOR FURTHER INFORMATION CONTACT:** For further information, contact William W. Thompson, II, Acting Administrator, Office of Foreign Labor Certification, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room C-4312, Washington, DC 20210; Telephone (202) 693-3010 (this is not a toll-free number). Individuals with

hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:**I. Background**

On April 15, 2015, the Employment and Training Administration (ETA) of the Department of Labor (DOL or Department) issued a notice of proposed rulemaking (NPRM) requesting comments on proposed standards and procedures to govern the certification of nonimmigrant workers in temporary or seasonal agricultural employment under the H-2A program. Temporary Agricultural Employment of H-2A Foreign Workers in the Herding or Production of Livestock on the Open Range in the United States, 80 FR 20300 (2015). Specifically, the NPRM addressed employment in sheep, goat and cattle herding occupations performed on the open range.¹ ETA invited written comments on all aspects of the proposed regulations from interested parties. ETA also invited public comment on a variety of specific issues. Originally, the written comment period closed on May 15, 2015. However, in response to many requests for additional time in which to comment, ETA extended the comment period through June 1, 2015. ETA has reviewed and considered all timely comments received in response to the proposed regulations.

The Department received 506 timely comments from a wide variety of sources. Commenters included: Members of Congress; State political officials, including State governors and legislative representatives; State executive agencies; individual ranchers that employ H-2A herders in their operations; national and state-level industry advocacy organizations; worker advocacy organizations; national and state-level agriculture advocacy organizations; wool growers associations; sheep shearing businesses;

¹ As discussed in greater detail below in Sec. IV.A.3.c., we have modified the definition of "open range" based on a significant number of comments addressing the issue, and the Final Rule now refers to these herding occupations as work on the "range." However, when discussing this requirement as it appeared in the former rules or in the proposed provisions in the NPRM, we rely on the prior references to the "open range." In addition, ETA has traditionally referred to the production of cattle separately as the "open range production of livestock." For ease of reference, and because this Final Rule concludes that the work involved in sheep, goat and cattle production, including herding, can be treated similarly for the purposes of this regulation, we may also refer to the "range production of livestock" as "cattle production," which includes "cattle herding."

members of the media; and the Small Business Administration's Office of Advocacy (SBA Office of Advocacy), among others. The vast majority of comments specifically addressed issues contained in ETA's proposed rule. The Department recognizes and appreciates the value of comments, ideas, and suggestions from all those who commented on the proposal, and this Final Rule was developed only after consideration of all the material submitted.

II. Statutory and Regulatory Authority

The Immigration and Nationality Act (INA or the Act) establishes the H-2A visa classification for employers to employ foreign workers on a temporary basis to perform agricultural labor or services. INA Section 101(a)(15)(H)(ii)(a), 8 U.S.C. 1101(a)(15)(H)(ii)(a); *see also* INA Secs. 214(c)(1) and 218, 8 U.S.C. 1184(c)(1) and 1188. The INA authorizes the Secretary of the Department of Homeland Security (DHS) to permit the admission of foreign workers to perform agricultural labor or services of a temporary or seasonal nature if the Secretary of the Department of Labor (Secretary) certifies that:

(A) There are not sufficient workers who are able, willing, and qualified, and who will be available at the time and place needed to perform the labor or services involved in the petition; and

(B) The employment of the foreign worker(s) in such labor or services will not adversely affect the wages and working conditions of workers in the United States similarly employed.

8 U.S.C. 1188(a)(1).

The Secretary has delegated these responsibilities, through the Assistant Secretary, Employment and Training Administration (ETA), to ETA's Office of Foreign Labor Certification (OFLC). Sec. Order 06-2010, 75 FR 66268 (Oct. 27, 2010). The Secretary has delegated responsibility for enforcement of the worker protections to the Administrator of the Wage and Hour Division (WHD). Sec. Order 01-2014, 79 FR 77527 (Dec. 24, 2014).

Since 1987, OFLC and its predecessor agencies have operated the H-2A program under regulations promulgated under the authority of the Immigration Reform and Control Act of 1986 (IRCA), which amended the INA and established the H-2A program.² OFLC's

² The Immigration and Nationality Act of 1952 created the H-2 temporary worker program. Public Law 82-414, 66 Stat. 163. In 1986, IRCA divided the H-2 program into separate agricultural and non-agricultural temporary worker programs. See Public Law 99-603, sec. 301, 100 Stat. 3359 (1986). The H-2A agricultural worker program designation

current regulations governing the H-2A program were published in 2010 following notice and comment. 75 FR 6884 (Feb. 12, 2010) (2010 Final Rule). Historically, and as provided in 20 CFR 655.102 of the 2010 Final Rule, the H-2A regulations permitted OFLC to set “special procedures” to govern the employment of foreign workers in certain occupations, such as sheep and goat herding and the range production of livestock, to which the standard H-2A regulations did not readily apply, so long as the special procedures adhered to the statutory mandates to determine U.S. worker availability and to certify that bringing in foreign workers will not adversely affect the wages and working conditions of workers in the United States similarly employed. 8 U.S.C. 1188(a)(1). The Department’s history of setting standards and procedures applicable to range herding or production of livestock occupations through Training and Employment Guidance Letters (TEGLs) and predecessor sub-regulatory guidance documents is set out in extensive detail in the NPRM, 80 FR at 20301–20302, and we do not repeat it here.³ However, as a result of a recent court decision, *Mendoza et al. v. Perez*, 754 F.3d 1002 (D.C. Cir. 2014), ETA is now establishing the standards that govern H-2A herder occupations in this Final Rule through notice and comment rulemaking. The new regulations will be incorporated at 20 CFR part 655, subpart B.

III. Discussion of General Comments

This preamble sets out DOL’s interpretation of the new regulations added to Subpart B, section by section. Before setting out the section-by-section analysis below, however, we will first acknowledge and respond to comments that did not fit readily into this organizational scheme.

A. General Comments

Most of the hundreds of comments we received addressed one or more specific issues in the NPRM, such as the proposed wage methodology, all of which are discussed in greater detail in Sec. IV below. However, within many of those targeted comments were more general remarks on the nature and the scope of the proposed rule, as discussed here. We received several general comments in support of the NPRM and the proposed standards and procedures.

corresponds to the statute’s agricultural worker classification in 8 U.S.C. 1101(a)(15)(H)(ii)(a).

³ This Final Rule supersedes the two TEGLs that currently govern the temporary employment of foreign herders, TEGL No. 32–10 (Jun. 14, 2011) and TEGL No. 15–06, Change 1 (Jun. 14, 2011).

Several commenters indicated that new rules were necessary to improve wages and other conditions for workers and to monitor compliance with the regulations. Some commenters noted that the new regulations were long overdue, in particular because foreign workers in herder occupations are grossly underpaid. One commenter noted that although herders’ wages should be increased, the upward adjustment should be implemented over a period of time so that employers can adapt to the wage increase.

The vast majority of comments we received were from individuals or organizations that opposed specific aspects of the NPRM’s provisions, particularly the wage methodology. Many of the comments were from individual ranchers who stated that their families had been operating their businesses for five or more generations. From a review of these comments, several overarching general themes emerged. Several commenters observed that the current rules “are not broken,” so no fix is required. Dozens of commenters remarked that the proposed wage methodology would result in the loss of livelihood of many individual ranchers, and dozens of others went further to conclude that the proposed wage methodology would put an end to the production of sheep, goat and cattle industries in the United States as a whole. Many commenters noted that satellite industries that provide goods and services to or derive goods and services from sheep, goat and cattle production, including textiles businesses and wool mills; the production of military, sports, and first responder uniforms from sheep wool; meat processing; feed lots; animal transport; veterinarians and vet supplies; and seed stock producers, among others, would be adversely effected by the new regulation. Others noted that in addition to the impact on satellite industries, the communities in which the regulated ranches are located would suffer, because the ranches stimulate the local economy through the purchase of goods, supplies and services locally to sustain their businesses, including banking services, grocers and gas stations, among others. The adverse impact to both the satellite industries and the local communities would include, the comments noted, the loss of jobs to U.S. and foreign workers alike. One comment noted that with increased costs to ranchers, which would result in loss of livestock-based jobs, land grant colleges with agriculture programs would suffer.

We received many comments that addressed the international aspects of

the herder occupations and the industries that employ them. One commenter noted that the foreign labor certification program creates goodwill between the United States and the foreign workers’ countries of origin, and the new rules would diminish that goodwill. Several comments noted the impact of foreign imports, particularly sheep imports, on the ability of U.S. ranchers to compete in the global marketplace. These comments suggested that if herder wages are increased, the government must also protect the U.S. market from price competition resulting from less expensive foreign imports. Many ranchers remarked that foreign importers would further profit because foreign producers would undercut U.S. meat and wool prices. Commenters also asserted that foreign meat imports are not held to the same food safety standards as U.S. meat producers, which increases the cost of the domestic products.

We also received several dozen comments about the environmental impact that would result if the sheep, goat and cattle industries experience increased costs to employ herders. One commenter noted that grazing livestock producers manage 250 million acres of Western land, including public land under the stewardship of the U.S. Forest Service (USFS or Forest Service) in the U.S. Department of Agriculture and the Bureau of Land Management (BLM) in the U.S. Department of the Interior. Many of these comments noted that the migratory pattern of animal herding is itself a natural resource management activity. Among the natural resource management benefits of controlled animal migration are the improvement of wildlife habitats that promotes animal breeding and sustains migratory fowl; the control of the spread of noxious and invasive weeds; the reduction of the use of herbicides and pesticides; the increased use of sheep “fertilizer” to improve the quality of the land; and the decreased use of machinery for tending the land, thus reducing fuel use and our carbon footprint. Several dozen comments indicated that animal grazing aids in the reduction of undergrowth that feeds wildfires in the West. Thus, these commenters asserted that if sheep, goat and cattle producers’ costs are raised, this would result in the reduction of animal grazing overall, which would, in turn, increase wildfires in the Western United States because of the abundance of “fuel” that would otherwise be reduced by grazing. Such fires would, among other things, result in the devastation of sage brush, which is the

habitat of sage grouse that nest in grasslands across the American West. Other commenters noted that without regular grazing, invasive weeds would overtake Western grasslands. One comment indicated that if ranchers' costs are increased, ranch land would be sold, and developers would build tract housing. The land management issues offered by these comments raise important questions about the role of animal grazing and care of our natural resources. This Final Rule is limited to the regulation of particular issues dealing with the employment of herders, but we have consulted with our sister agencies, USFS and BLM, about particular issues addressed in this Final Rule, including the proposed definition of "open range," discussed further below in Sec. IV.A.3. of the section-by-section analysis.

Many ranchers noted that, in their view, foreign herders are satisfied with their current wages and working conditions. In support of this conclusion, they indicated that the wages earned are far superior to those wages they might earn for the same work in their countries of origin. Ranchers noted that their foreign workers routinely send funds home, suggesting that the herders have expendable income. They also noted that the same herders return to their U.S. jobs year after year, suggesting that the wages and working conditions are satisfactory to support the retention of foreign herders. Several ranchers noted that herders become "one of the family" and are welcome in the ranch house to take meals with the family, and that employers take good care of herders' health and welfare. To this end, we received several comments inviting us to visit the ranches and the herders so that we could better understand the industry and the way of life. Several ranchers indicated that if there were, in fact, exploitive ranch operations that did not "play by the rules," DOL should take action against those ranchers but not change the current rules.

We received several comments requesting that we "work closely" with the industry to develop "workable new rules." Prior to this notice and comment proceeding, we received and considered written input from the industry, as well as employee advocates, in developing the provisions proposed in the NPRM. 80 FR at 20309. We have also reviewed and considered carefully all 506 comments received from the stakeholders affected by this Final Rule, including both industry and employee representatives. We address in more detail below, particularly in the section on the wage methodology adopted in

the Final Rule, the concerns raised about the adverse impact of the regulation on ranchers, their local communities, and other industries that serve the ranching industries. As we discuss more fully below, we recognize that after decades of the status quo, in which there was no change to the rules governing these industries, the current modernization effort can have a broad impact, and we have made adjustments to the proposed provisions, as discussed more fully below, with these interests in mind, as well as those of the employees. We thank all commenters for their input, including those that offered their general support for and their opposition to the new regulations, and we have considered all these remarks as we developed the provisions included in this Final Rule.⁴

B. Mendoza v. Perez and the Need for Rulemaking

The NPRM indicated that among the reasons for the current rulemaking was the decision in the *Mendoza* case, cited above. That case required the Department to engage in notice and comment rulemaking to set standards governing the employment of foreign herders because those standards were legislative rules governed by the Administrative Procedure Act, 5 U.S.C. 553. *Mendoza*, 754 F.3d at 1024–1025. We received several comments to the effect that although the *Mendoza* case required the Department to engage in notice and comment rulemaking, that case did not require the Department to alter the substantive standards that currently govern the employment of foreign herders as set out in the applicable TEGs. These comments note that we could have simply proposed the current TEG standards without change, and asked for comment on those provisions.

We agree that the *Mendoza* case only required us to engage in notice and comment rulemaking, but did not

⁴ We note that we received several general comments about issues outside the scope of the present rulemaking. One comment asserted that this rulemaking "sets a dangerous precedent" for regulating the beekeeping and custom combine harvesting industries that also employ H-2A workers. Another comment indicated that the United States needs "immigration reform," but did not specify the nature of that reform. One comment asserted that the government should not be involved at all in agriculture, that the "open market" should control, and that "government supports" for sheep and cattle ranchers should be removed. One commenter submitted that employers should be required to provide herders with two weeks of paid vacations. Finally, three comments suggested that DOL should expand the H-2A program to include other year-round animal agriculture, including dairy production. As noted, these comments all address issues that are not within the scope of this rulemaking.

require us to alter the standards as they were set in the applicable TEGs. However, the NPRM provided reasons other than the *Mendoza* case to support notice and comment rulemaking initiated by a proposal that substantively altered the standards long governing herding occupations. As noted in the NPRM, ETA's traditional method of determining the prevailing wage for these occupations—the use of surveys by the state workforce agencies (SWAs)—has become increasingly difficult. In these occupations the prevailing wage has served as the Adverse Effect Wage Rate (AEWR). Few survey results are produced, which casts doubt on the statistical validity of those surveys. 80 FR at 20302, 20307. New wage methodology standards were needed to establish "a more effective and workable methodology for determining and adjusting a monthly [wage] for these unique occupations[.]" 80 FR at 20302. In addition, because of the difficulty in setting the wage under the prior methodology based on the SWA surveys, herder occupations have experienced "wage stagnation in various degrees across these occupations[.]" 80 FR at 20307. In many cases, herders whose wages are set under the current standards are making only slightly more in nominal wages than they were 20 years ago, and therefore are making significantly less in real terms today. *Id.* Therefore, we needed to engage in notice and comment rulemaking not only as a result of *Mendoza*; we also needed to address the inadequate wage methodology that over years contributed to herder wage stagnation. It is a reasonable exercise of DOL's discretion to propose a new wage methodology in the NPRM on which commenters could and did provide input.

We received two joint comments from worker advocate groups that supported the need for rulemaking, particularly to address the inadequate wage methodology and herder wage stagnation. A relatively brief worker advocate joint submission applauded the proposed rules, asserting that the revisions will "greatly benefit both temporary foreign workers and U.S. workers alike, including long-overdue wage increases and other proposed provisions that seek to address the poor working conditions."⁵ A more

⁵ Fifty-four groups and three individuals were signatories to this 4 page joint employee advocate comment providing input on wages, housing, food, employer-provided items, experience requirements, and a few other issues. The signatories to this joint comment were American Federation of Labor and Congress of Industrial Organizations (AFL-CIO); California Church IMPACT; California Rural Legal Assistance Foundation; CATA—EL Comité de

comprehensive worker advocate joint comment submitted the same day, which included many of the same signatories as the other worker advocate joint comment, supported the rulemaking as necessary to revise the current wage methodology that has produced wage stagnation over a period of years.⁶ This comment stated that DOL has relied on old data and outdated surveys, with sample sizes that are too small to be statistically valid. This comment identified problems with the wage-setting method under the TEGLs, including permitting reliance on prior years' surveys and basing the wage on neighboring states where no survey results were available. This comment

Apoyo a los Trabajadores Agrícolas/The Farmworker Support Committee; Catholic Migrant Farmworker Network; Central-West Justice Center, Migrant Farmworker Program; Centro de los Derechos del Migrante, Inc.; Church of the Brethren, Office of Public Witness; Coalition of Immokalee Workers; Coalition to Abolish Slavery & Trafficking; Cumberland Presbyterian Church Missions Ministry Team; Disciples of Christ Refugee and Immigration Ministries; Dominican Sisters and Associates of Peace; Eastern Regional Alliance of Farmworker Advocates; Equal Justice Center; Farmworker Association of Florida; Farmworker Justice; Food Chain Workers Alliance; Franciscan Sisters of Little Falls Justice & Peace Commission; Friends of Farmworkers, Inc.; Global Workers Justice Alliance; Greater Rochester Coalition for Immigration Justice; Immigrant Worker Project—Ohio; Jobs With Justice; La Union Del Pueblo Entero; Labor Council for Latin American Advancement; Legal Aid Services of Oregon; Líderes Campesinas; National Guestworkers Alliance; National Consumers League; National Council of La Raza (NCLR); National Employment Law Project; National Farm Worker Ministry; North Carolina Farmworkers Project; New Mexico Center on Law and Poverty; New Mexico Legal Aid; National Farm Worker Ministry; Northwest Workers' Justice Project; Office of Justice, Peace and the Integrity of Creation at the Stuart Center; Orange County Interfaith Committee to Aid Farm Workers; PathStone Corporation; Piñeros y Campesinos Unidos del Noroeste (PCUN); Polaris Project; Public Citizen; Public Justice Center; Puerto Rico Legal Service Migrant Worker Project; Ramsay Merriam Fund; Rural Neighborhoods; Sisters of Charity of the Blessed Virgin Mary; Dubuque Iowa; Telamon Corporation; Towards Justice; The Episcopal Church; United Farm Workers; United Migrant Opportunity Services; Sergio Velasquez Catalan (one of the named plaintiffs in *Mendoza v. Perez*, No. 11-cv-01790 (D.D.C. May 7, 2015)); Thomas A. Arcury, Ph.D., Professor; Susan Gzesh, Senior Lecturer & Executive Director, Pozen Family Center for Human Rights, University of Chicago.

⁶ Fourteen groups and three individuals were signatories to a 35 page employee advocate joint comment with attachments, and included California Rural Legal Assistance; California Rural Legal Assistance Foundation; Central California Legal Services; Colorado Legal Services, Community Legal Services of Arizona; Farmworker Justice; Florida Legal Services; Global Workers' Alliance; Jennifer J. Lee, Assistant Clinical Professor of Law, Temple University Beasley School of Law; Legal Aid Services of Oregon; Northwest Justice Project; Southern Minnesota Regional Legal Services; Texas RioGrande Legal Aid; United Farm Workers; Utah Legal Services; Zacarias Mendoza and Francisco Castro (two of the plaintiffs in *Mendoza v. Perez*, No. 11-cv-01790 (D.D.C. May 7, 2015)).

also identified the failure to filter out the wages of H-2A nonimmigrants in the survey results, and errors and inconsistencies in the SWA surveys (which, the comment indicates, may be a misclassification of workers) as contributing to wage stagnation. The comment suggested that the methodology is flawed and has cost herders "millions of dollars." Although much of the specific substance of this comment will be discussed below in the section-by-section analysis, DOL concurs with the general theme of both employee advocate joint comments that, apart from the *Mendoza* case, this rulemaking is warranted to address problems with the wage methodology and herder wage stagnation, as we stated in the NPRM.⁷

C. Historical Background of Foreign Herder Employment

We received several comments, including from industry associations Mountain Plains Agricultural Services (Mountain Plains) and Western Range Association (Western Range) that address the early history of foreign sheep herders coming into the United States to perform herding work, as early as the 1950s. The NPRM discussed this history in some length. 80 FR at 20301–20302. Based on the history, one commenter noted that early herders from the Basque region in Spain were given special treatment in order to permit their entry into the United States to work when no U.S. workers were available, which gave rise to the establishment of special procedures. Three commenters underscored that Congress recognized the special needs of sheep ranchers in their early enactments in the 1950s. Two commenters indicated, without specific citation, that IRCA intended that DOL grant special procedures to ranchers seeking foreign herders. One commenter asserted that foreign herders should be permitted to stay in the United States longer than typically allowed because of the unique skills of foreign herders. One commenter submitted that the history of special procedures, as reflected in early Congressional action, DOL sub-regulatory action, and subsequent regulations permitting the establishment of special procedures, provides a sound foundation for the continuation of

⁷ We have reviewed and considered both employee advocate joint comments. Because the comprehensive joint comment essentially addressed all the subjects that the shorter one did and in greater detail, and because there is a good deal of overlap in the signatories, when referencing the joint comments of the employee advocates, we will refer to them as the "Worker Advocates' Joint Comment."

special procedures. Several commenters noted that the process and standards set out in early Departmental guidance and later incorporated into the TEGLs have worked well for decades and that change is unnecessary. These commenters noted that special procedures—separate from the regular H-2A standards—are necessary because of the recognized unique nature of the herding occupation, including that herders tend to the herd all day, every day, and that their remote location makes their work hours difficult to record. Finally, the Worker Advocates' Joint Comment pointed out that even though separate regulatory standards may be required because of the nature of herding work, those variances from the standard H-2A requirements must apply only to herders working on the range and not to livestock workers on the ranch. They further note that the variances must be consistent with the statutory command to protect against adverse effect on U.S. workers' wages and working conditions. As with the proposal in the NPRM, we have taken into account the unique nature of herder work and its long history with respect to the employment of foreign workers as we developed this Final Rule.

D. Requests for Extensions of Time to Submit Comments

We published the NPRM on April 15, 2015 and originally requested that comments be submitted within 30 days, by May 15, 2015. We received 100 comments requesting an extension of the public comment period. A plurality of requests to extend the comment period (48) did not identify the specific time period sought for an extension. However, 38 requests sought an extension of the comment period for 90 days. The remainder of the requests sought additional time variously in a range between 30 and 180 days.

On May 5, 2015, we extended the comment period an additional 15 days, to June 1, 2015. 80 FR 25663. We received a few additional comments (counted in the 100-request total mentioned above) seeking time beyond the new June 1, 2015 deadline. However, because of the *Mendoza* court scheduling order, we were not able to extend the public comment period beyond June 1, 2015 to submit comments.⁸ However, as noted, we

⁸ The original scheduling order, dated October 31, 2014, required DOL to issue an NPRM by March 1, 2014, and a final rule by November 1, 2015, with an effective date no later than December 1, 2015. The revised scheduling order, dated February 25, 2015, required DOL to issue an NPRM by April 15, 2015, but maintained the requirement that we issue

Continued

received 506 unique comments during the allotted comment period, addressing all aspects of the NPRM, which is a robust response given the 45-day comment period.

IV. Section-by-Section Summary of the Final Rule, 20 CFR Part 655, Subpart B

This preamble sets out ETA's interpretation of the new regulations in Subpart B, section by section, and generally follows the outline of the regulations. Within each section of the preamble, the Department has noted and responded to those comments that are addressed to that particular section of the rule. The Department notes that, in the NPRM, we had proposed to place these new rules in a new Subpart C. In order to ensure that there is no confusion regarding the Department's continued authority to enforce requirements relating to herding and range livestock workers pursuant to 29 CFR part 501, we have decided to place the new rules at the end of existing Subpart B, the standard H-2A requirements, rather than in a new Subpart. Therefore, ministerial conforming modifications have been made throughout the regulation to accommodate this non-substantive change. Such minor modifications are not addressed individually below.

A. Introductory Sections

1. Section 655.200—Scope and Purpose of Herding and Range Livestock Regulations

As stated in the NPRM, the standard H-2A regulations in existing 20 CFR part 655, subpart B (§§ 655.100—655.185) govern the certification of employers' temporary employment of nonimmigrant workers in temporary or seasonal agricultural employment. Because of the unique nature of the herder occupations, employers who seek to hire temporary agricultural foreign workers to perform herding or production of livestock on the range, as described in § 655.200(b), are subject to certain standards that are different from the regular H-2A standards and procedures. These new regulations, found at §§ 655.200–655.235 (hereinafter generally referred to as the herding and range livestock regulations), are intended as a comprehensive set of regulations governing the certification of the temporary employment of foreign workers in herder or production of livestock occupations on the range.⁹

a final rule by November 1, 2015, with an effective date no later than December 1, 2015.

⁹ Some States have set employment standards governing agriculture employment generally, or

However, to the extent that a specific variance from the standard H-2A requirements is not set out specifically in the new herding and range livestock provisions, the standards and procedures set forth in the standard H-2A regulations apply.

Prior to this Final Rule, the standards and procedures governing sheep, goat and cattle herders were set separately in two different TEGLs, as noted above. Although there were some differences in the TEGL standards as they applied to the different industries (sheep and goat herding were covered by one TEGL and cattle herding by the second TEGL), the standards and procedures were largely the same. We proposed in the NPRM to set the same certification standards and procedures for employers employing foreign sheep and goat herders as employers employing foreign cattle herders. We received two comments on this issue. The first was included in the Worker Advocates' Joint Comment, which concurred that a single set of rules is needed to protect goat herders, sheep herders, and range production of livestock workers efficiently and effectively. The second comment, submitted by Maltsberger Ranch, opposed applying the same standards to sheep and goat herding, and open range production of livestock.

Maltsberger Ranch indicated that the rules should be different because the animals' "husbandry, needs and handling standards are different, [and an] area's geographic location may dictate the need of different ranching practices. . . . The rule should not be rewritten in a manner that changes the scope of, or redefines the application of special procedures historically granted [to] Range Producers of Livestock." We are adopting the position taken in the NPRM, which sets common procedures and other standards for sheep and goat herding, and open range production of livestock. The common standards and procedures will improve the requirements' clarity and readability, streamline application processing, and improve compliance, all without hindering variations in employer practices or impairing employee rights or employer obligations. Accordingly, as proposed in the NPRM, the herding and range livestock regulations apply to employers seeking certification of

herder employment more specifically, and those standards may differ from the standards set in this Final Rule. The terms and conditions of herder employment established in this Final Rule are intended as a floor and not a ceiling. *See, e.g.*, 29 U.S.C. 218(a). Accordingly, where a State sets employment standards applicable to herders that are higher (more protective) than those set in this Final Rule, DOL intends that the State standards should apply.

applications to employ foreign herders to tend sheep, goats and cattle on the range.

2. Section 655.200(b)—Jobs Subject to Herding and Range Livestock Regulations

a. Background

In order to use the herding and range livestock regulations, an employer's job opportunity must possess all of the characteristics described in this provision. The TEGL for sheep and goat herding occupations and the TEGL for open range production of livestock repeatedly refer to the unique characteristics of these occupations as the bases for the special procedures. The TEGL for sheep and goat herding occupations describes the unique characteristics of herding as "spending extended periods of time with grazing herds of sheep in isolated mountainous terrain; being on call to protect flocks from predators 24 hours a day, 7 days a week . . ." TEGL 32-10, 3. The TEGL for open range livestock production also states that these occupations "generally require workers to live in remote housing of a mobile nature, rather than 'a fixed-site farm, ranch or similar establishment.'" TEGL 15-06, Change 1, Appendix B, I. Both TEGLs require that the Form ETA-790 submitted to the SWA include that the anticipated hours of work are "on call for up to 24 hours per day, 7 days per week." TEGL 32-10, Attachment A, I(C)(1); TEGL 15-06, Change 1, Attachment A, I(C)(1). Both TEGLs also require that employers provide effective means of communication with workers "due to the remote and unique nature of the work to be performed." TEGL 32-10, Attachment A, I(C)(4); TEGL 15-06, Change 1, Attachment A, I(C)(4). As discussed more fully in Sec. IV.A.3. of the preamble related to § 655.201, both TEGLs also provide descriptions of job duties that employers may use when submitting their Form ETA-790 to the SWA.

Section 655.200(b) of the NPRM proposed to limit the scope of jobs subject to these rules by requiring that: (1) the work activities involve the herding or production of livestock and any additional duties must be "minor, sporadic, and incidental to the herding or production of livestock"; (2) the "work is performed on the open range requiring the use of mobile housing" for "at least 50 percent of the workdays in the work contract period" and "[a]ny additional work performed at a place other than the range . . . that does not constitute the production of livestock must be minor, sporadic and incidental

to the herding or production of livestock;" and (3) the "work activities generally require the workers to be on call 24 hours per day, 7 days per week." 80 FR at 20339. The NPRM also proposed to require that job orders include "a statement that the workers are on call for up to 24 hours per day, 7 days per week and that the workers are primarily engaged (spend at least 50 percent of the workdays during the contract period) in the herding or production of livestock on the open range." *Id.* Proposed § 655.210(b) also provided that duties "may include activities performed at the ranch or farm only if such duties constitute the production of livestock or are closely and directly related to herding and the production of livestock. Work that is closely and directly related to herding or the production of livestock must be performed on no more than 20 percent of the workdays spent at the ranch in a work contract period. All such duties must be specifically disclosed on the job order." *Id.*¹⁰

In the Final Rule, the Department eliminates the 50 percent mobile housing requirement, and requires that herders spend more than 50 percent of their workdays on the range, which is more consistent with the exemption in the Fair Labor Standards Act (FLSA) for range production of livestock, as discussed below. We have also retained the requirement that the work activities generally require the workers to be on call 24 hours per day, 7 days a week. As discussed in more detail below in Sec. IV.A.3., in which we address § 655.201, "Definition of terms," we have deleted the definition of "minor, sporadic and incidental" duties and removed the 20 percent cap on such closely and directly related duties.

b. Comments

A number of commenters addressed the requirement that the work be performed on the open range requiring mobile housing for at least 50 percent of the work days in the contract period. Some commenters addressed the 50 percent requirement directly and others provided information regarding the times of year workers typically spend on and off the range or in mobile housing.

Commenters directly addressing the 50 percent range requirement primarily raised concerns with the combined effect of the 50 percent range

requirement and the proposed definition of "open range" (which generally included the absence of fencing as a required element of open range, which is discussed further below); they stated that many operations currently using the TEGs would no longer qualify for the program because of the prevalence of fencing on the range. That is, commenters explained that it is almost impossible to spend at least 50 percent of the contract period away from fences. For example, the Garfield County Farm Bureau (GCFB) commented that the 50 percent range requirement "simply does not work for many of our members." The GCFB explained that many producers run their operations on private fenced and unfenced parcels, and are only using "large acre non-fenced permits" for late spring and summer, thus not meeting the 50 percent range requirement. Silver Creek Ranch explained that fences are prevalent throughout their herding operations, so to regulate the time herders are in contact with fences or enclosed areas would be impractical and could impair the quality of the care provided to the livestock. The Wyoming Livestock Board explained that many producers graze on crop residue, private leases, vineyards and other parcels near populated areas, and that if "herding can only take place where no fences exist, for at least 50 [percent] of the work time[,] a majority of range sheep operations would not be eligible for H-2A herders."¹¹

Several commenters, including the Idaho Wool Growers Association, stated that the NPRM's dual requirements of no fencing and that the herders must spend half of the year away from headquarters and livestock facilities would disqualify many herders from using these regulations. These commenters primarily discussed the fencing issue and did not elaborate on whether herders typically spend more than 50 percent of the work contract at a fixed site on a ranch or farm. For example, the Texas Sheep & Goat Raisers' Association (TSGRA) stated that "the proposal suggests that no fences would be allowed in connection with sheepherders and, further, half of the herders' year must be away from the ranch headquarters and livestock facilities." TSGRA further explained that "private grass, supplemental hay and crop aftermath are the available options to maintain year-round feed for

the animals and that does not fit the Department's apparent view of grazing out of sight of fencing or facilities."

Some commenters stated that the 50 percent rule is "unworkable" or an "administrative nightmare" and does not allow for flexibility in cases of bad weather, emergencies, or other circumstances. For example, Henry Etcheverry, a sheep rancher, described the recordkeeping associated with the 50 percent rule as "impossible" and explained that each operation varies and thus requires different times spent in mobile housing or at the ranch. Brian Clark, an employee of the Wyoming State Workforce Agency representing his own views, stated that using percentages to determine how much time is spent on the range could create an "administrative and enforcement nightmare," does not reflect reality, and does not reflect the FLSA criteria. Peter and Beth Swanson, commercial sheep producers, commented that many of their grazing locations are neither a "ranch site" nor "open range" (as defined in the NPRM) and that time spent on the "open range" depends on range forage availability, which varies due to a number of circumstances, such as rainfall, weather conditions, and land owner decisions. Mountain Valley Livestock stated that time spent in mobile housing versus at headquarters can be completely dependent on the weather.

Mountain Plains and Western Range, in a comment adopted by several other commenters, specifically addressed the 50 percent mobile housing requirement, calling the rule "arbitrary and unworkable." In their view, a sheepherder spending 182 days of the year in mobile housing but the rest in a bunk house during other livestock production work would not be eligible under either the special procedures or the standard H-2A program. Mountain Plains and Western Range further commented that, as mobile housing was defined in the NPRM, a limited number of range cattle operations in Montana and Texas currently using the special procedures may not be eligible for the new herding and range livestock regulations, as they use non-mobile range housing on the range for livestock workers. However, they acknowledged that virtually all employers use mobile housing except for this small subset.

Mountain Plains and Western Range recommended that instead of the 50 percent range/mobile housing and 20 percent minor, sporadic, and incidental limitations, the Department adopt the FLSA range production exemption from minimum wage and overtime "principally engaged" rule. *See* 29

¹⁰ The Department is addressing here the NPRM provisions in § 655.200(b) as well as the corresponding proposed job order disclosures found in § 655.210(b), as these issues and comments overlap. The remainder of the provisions of proposed § 655.210, "Contents of job orders," are addressed below in a separate discussion.

¹¹ We received a substantial number of comments addressing the proposed definition of "open range" and describing the prevalence of fencing in modern herding. Those comments are discussed in further detail below, in Sec. IV.A.3. of the preamble related to § 655.201, "Definition of terms."

U.S.C. 213(a)(6)(F), 29 CFR 780.325. Under the FLSA, a worker spending more than 50 percent of his or her time on the range is exempt, even if the employee performs some duties on the ranch not closely or directly related to herding or the production of livestock. 29 CFR 780.325. Mountain Plains and Western Range commented that the FLSA exemption is “less confusing and more workable” than the “arbitrary” percentage limitations in the NPRM, as well as more “holistic and flexible,” and, in their view, focuses on the duties of the worker rather than the location of the work. They commented that the FLSA test would be better understood and more likely complied with by employers.

The Department received a small number of additional comments specifically addressing the requirement to spend 50 percent of the work contract period in mobile housing; however, none of these comments supported the proposed requirement. As Mountain Plains and Western Range explained, a small number of their members use non-mobile range housing rather than mobile housing and thus would be ineligible to apply under these regulations. The Worker Advocates’ Joint Comment commented that the 50 percent mobile housing requirement is unnecessary, and that this requirement could have the unintended effect of inducing employers to house workers in mobile housing when fixed site housing is otherwise available.

Several commenters provided detailed information regarding time typically spent on the ranch versus the range. These comments, considered together, demonstrate that herding and production cycles vary greatly among operations, and a certain amount of flexibility is warranted to allow for differing amounts of time spent at the ranch. However, despite many of the commenters expressing concern with a 50 percent range requirement (largely due to the issue of fencing), these comments demonstrate that most operations appear to be spending more than 50 percent of the work contract period on land considered “range,” if fencing is permissible. For example, W.F. Goring & Son commented that they run their sheep on the open range about 80 percent of the time and the remaining 20 percent of the time is “spent on private lambing grounds where our animals are divided into large fenced pastures.” The Siddoway Sheep Company spends approximately two to three months at the ranch for lambing, then spring and fall grazing are conducted on BLM-permitted lands, state lands and private lands, and

summer grazing is in the high mountain meadows. Larson Livestock stated that it grazes sheep on the open range for twelve months of the year.

In contrast to the above comments, the Worker Advocates’ Joint Comment agreed that the “Department’s attempt to specifically delineate the kinds of jobs that fall under [the proposed rule] is long overdue and sorely needed.” However, they expressed concern with the 50 percent threshold, asserting that this provision will adversely impact the wages and working conditions of U.S. workers because it allows too much time off the range and creates a loophole allowing employers to pay the herding and range livestock wage for up to six months of work on the ranch. The advocates explained that “H–2A and comparable U.S. workers, who do not work on the range (ranch hands), would otherwise be classified as ‘Farmworker, Livestock . . . They would not fall under [these rules] and would be entitled to be paid at the hourly AEWR rate . . . That work, if offered apart from the on the range herding work is more likely to attract U.S. workers.” They recommended that the Department revise the rule to require that 70 percent of the work contract period be spent on the range.

A number of commenters also addressed the requirement that the work activities generally require workers to be on call up to 24 hours per day, 7 days per week. These comments overwhelmingly support the conclusion that these occupations require herders and range livestock production workers to be on call at all times while on the range to protect and manage the herd, one of the unique characteristics of these occupations. The Texas Sheep & Goat Raisers’ Association emphasized the on call nature of the job as central to herding, stating, “[s]heep ranching on rangeland throughout the United States has always been an industry that has at its roots shepherders, which are on call 24 hours a day, 7 days a week, to protect livestock from predation and natural disasters.” The Washington Farm Bureau similarly stated that “the open range sheep and livestock herding industry is unique and requires special treatment” and that herders are constantly on call to protect the herd. However, some commenters stressed that although workers are on call “24/7,” they are not required to work every hour of the day. As Helle Livestock stated, “while herding doesn’t require constant attention to the sheep it does require a constant presence.” Southern Cross Ranches commented that “it is imperative for herders to be available on a 24/7 ‘on call’ basis for maintaining

herd integrity and predator control” but herders are “not expected to and don’t work 24/7.” Mountain Plains and Western Range commented that the term “on call” may be misleading and suggested that instead the Department use the term “available.” Although not specifically commenting on the 24/7 provision, the Worker Advocates’ Joint Comment stated that “[w]orkers must also be given time off at least every six months and as required for other H–2A workers, who cannot be required to work more than 6 days per week, while at the ranch.”

c. Discussion

As in the TEGs, these NPRM provisions recognized that herding and range livestock production occupations are unique and distinguishable from other H–2A occupations because they are conducted primarily in remote areas away from headquarters, require workers to be on call 24 hours per day, 7 days a week, and require certain unique job duties. Specifically, the Department included in the NPRM a requirement that at least 50 percent of the work contract period be spent on the range and in mobile housing. The purpose of this provision was to provide a sufficient threshold to confirm the unique, remote characteristics of these occupations, because herding and range livestock regulations are intended only to apply to workers who attend the herd as it grazes on the range, while also allowing for a realistic and workable amount of time at the ranch. The Department concluded that some delineation with respect to ranch versus range time was necessary because it has found in its investigations that some workers are spending extended amounts of time at the ranch while being paid the wage rate intended for range workers under these rules. The Department viewed the 50 percent threshold as a reasonable requirement, as it requires workers to be primarily on the range, is consistent with the FLSA range production of livestock exemption, and allows for flexibility in the cases of emergencies and changing circumstances.

The NPRM further proposed that if an employer violated the 50 percent range requirement, the employer would be in violation of its obligations under this part. 80 FR at 20303. Depending on all the facts and circumstances, the employer would have been responsible for compliance with all of the regular H–2A requirements, including the payment of the highest applicable wage rate for all hours worked, and the Department could have sought other remedies for the violation. *Id.*

Upon consideration of the all comments received on these issues, the Final Rule removes the requirement that workers be in mobile housing for at least 50 percent of the work contract period. The Department received no comments in support of this provision. We agree with the Worker Advocates' Joint Comment that this requirement is not essential to the 50 percent range requirement to confirm that workers being paid the herding and range livestock worker wage are engaged in work performed on the range, and could have an unintended consequence of employers housing their workers in mobile housing when fixed site housing is otherwise available. Further, the Department did not intend to exclude operations currently using the TEGs who use non-mobile range housing on the range from using these rules (assuming they are in compliance with the remainder of the requirements under this Subpart), as pointed out by Mountain Plains and Western Range. The issue of non-mobile range housing is addressed in greater detail below, in Sec. IV.E. of this preamble related to the discussion of § 655.230, "Range Housing." However, we conclude that the need for range housing is relevant to whether a particular area is considered range and have addressed this issue in the definition of "range," as discussed in greater detail below.

The Final Rule requires that workers spend a majority, meaning "more than 50 percent," rather than "at least 50 percent" as provided in the NPRM, of the workdays in the work contract period on the range, as range has been defined in the Final Rule. This change is intended to be more consistent with the range production of livestock exemption from minimum wage and overtime under the FLSA. However, the Department concludes that fully adopting the FLSA range production of livestock exemption "principally engaged" rule is inappropriate here, because it would allow these workers to perform duties at the ranch or farm beyond those duties constituting the production of livestock. The Department's consideration of the FLSA exemption, permissible duties and the 20 percent cap are further addressed below in Sec. IV.A.3. of the preamble related to the discussion of § 655.201.

The record demonstrates that a rule requiring a majority of the workdays under the contract to be spent on the range is appropriate and necessary to confirm that occupations under the herding and range livestock regulations, earning the required wage rate, are indeed uniquely remote and thus distinguishable from other H-2A

occupations. As discussed above, the use of these special procedures is contingent on these occupations posing unique challenges and circumstances, one of which is the remote nature of the job. We conclude that allowing employers to pay the herding and range livestock wage to workers who are spending more time on the ranch than on the range would be inappropriate and would have an adverse effect on U.S. workers, as this work would otherwise be offered at the standard hourly AEWR for all hours worked and thus be more likely to attract U.S. workers.

The Department concludes that a majority range requirement is sufficient to confirm the unique, remote nature of these occupations and distinguish herders from other H-2A occupations, such as ranch hands, while also allowing for necessary flexibility in modern herding to allow for changing circumstances on the range. Thus, the Department declines to increase the threshold of time required on the range to 70 percent, as suggested by worker advocates. The Department also concludes that a majority range requirement is reasonable and practical. It is consistent with the FLSA range production exemption, as proposed by Mountain Plains and Western Range (a suggestion adopted by several other commenters) and, as discussed above, many comments received on this issue provided evidence that operations currently using the TEGs are spending more than 50 percent of the contract period on grazing areas considered range, as now defined in the Final Rule. As discussed in detail below, the Department has revised the definition of "open range" to "range" and removed the presence of fencing as an indicator of whether land is "range." The Department concludes that the revised definition of "range" will address the majority of the comments received regarding the 50 percent range requirement, as they focused largely on the issue of fencing.

Although some commenters expressed concern with setting a certain required percentage of time on the range, we consider the majority range requirement to provide adequate flexibility to address changing circumstances due to weather, forage availability, and other factors. Allowing more than half of the work contract to be spent at locations other than the range while still being paid the herding and range livestock wage would be contrary to the Department's statutory mandate to determine whether U.S. workers are available for the job opportunity, and to provide that there is

no adverse effect on similarly employed U.S. workers. Of course, if there are employers who cannot meet the majority range requirement, they may still use the standard H-2A program to obtain workers. Moreover, such employers might be able to use these procedures for some portion of the year that meets the majority range requirement, and use the standard H-2A program for the remainder of the year; this would require filing at least two certification applications.

Additionally, the Final Rule retains the requirement that the work activities generally require the workers to be on call 24 hours per day, 7 days a week. The record fully supports that herding and range livestock production occupations continue to require constant attendance to the herd so that workers are on call 24/7. This is one of the unique characteristics of these occupations that distinguish these jobs from other H-2A occupations, and we conclude that it is appropriate to require that this be a characteristic of such jobs. With respect to the commenters who underscored that "on call" does not mean actively working, the Department agrees that "on call" does not mean working for 24 hours per day, seven days per week, and the current terminology, which has been used consistently in the TEGs for many years and is used in this final rule, reflects this distinction.

We decline to adopt the Worker Advocates' Joint Comment recommendation to require that workers must be given time off at least every six months and while at the ranch. The NPRM did not include any provisions requiring time off at certain intervals or while on the ranch, and the Department did not seek comment on any issues relating to mandatory time off. Therefore, the public has not had sufficient notice that such a provision was contemplated for the Final Rule and has not had the opportunity to comment on such provisions. Additionally, as discussed above, an essential characteristic of these job opportunities is that they require workers to be on call up to 24 hours per day, 7 days per week. However, the Department understands from its enforcement experience that workers often do receive days off while at the ranch and some comments indicate that some workers receive paid vacation time. We encourage employers to adopt or continue these practices.

As provided in the NPRM and noted above, where the job opportunity does not fall within the scope of herding and range livestock production, the employer must comply with all of the standard H-2A procedures. If an

employer submits an application containing information and attestations indicating that its job opportunity is eligible for processing under the herding and range livestock procedures, but it is later determined, as a result of an investigation or other compliance review, that the worker did not spend more than 50 percent of the workdays on the range, or that the worker's duties at the ranch do not constitute the production of livestock (as discussed more fully below), the employer will be in violation of its obligations under this part and, depending upon the precise nature of the violation, may owe back wages or be required to provide other relief. Depending upon all the facts and circumstances, including but not limited to factors such as the percentage of days the workers spent at the ranch, whether the work was closely and directly related to herding and the production of livestock, and whether the employer had violated these or other H-2A requirements in the past, the employer will be responsible for compliance with all of the standard H-2A procedures and requirements, including payment of the highest applicable wage rate, determined in accordance with § 655.122(l) for all hours worked. In addition, the Department may seek other remedies for the violations, such as civil monetary penalties and potentially debarment from use of the H-2A program.

3. Section 655.201—Definition of Herding and Range Livestock Terms

a. Definitions of “Herding,” “Production of Livestock,” and “Minor, Sporadic, and Incidental Work”

i. Background

The TEGL for sheep and goat herding occupations provides a standard description of job duties that employers may use when submitting their Form ETA-790 to the SWA. TEGL 32-10, Attachment A, I(C)(1). That job description includes duties such as: Attending the animals on the range or pasture; using dogs to herd the flock and round up strays; guarding the flock from predatory animals and from eating poisonous plants; examining the animals for signs of illness; administering vaccines, medications and insecticides; and assisting with lambing, docking, and shearing. It also provides that the workers “may perform other farm or ranch chores related to the production or husbandry of sheep and/or goats on an incidental basis.” The TEGL does not define “incidental.” The TEGL also states that any additional duties must be normal and accepted for the occupation.

The TEGL for the open range production of livestock also contains a standard job description listing similar duties related to the animals. TEGL 15-06, Change 1, Attachment A, I(C)(1). It also states that the worker may assist with irrigating, planting, cultivating, and harvesting hay, and that workers must be able to ride and handle horses and maintain their bearings in grazing areas. Finally, it provides that any additional job duties must be normal and accepted for the occupation. The TEGL does not place any limitation on the amount of time workers may perform these duties.

Section 655.201 of the NPRM proposed to define “herding” as the “[a]ctivities associated with the caring, controlling, feeding, gathering, moving, tending, and sorting of livestock on the open range.” 80 FR at 20339. The NPRM proposed to define the “production of livestock” as the “care or husbandry of livestock throughout one or more seasons during the year, including guarding and protecting livestock from predatory animals and poisonous plants; feeding, fattening, and watering livestock, examining livestock to detect diseases, illnesses, or other injuries, administering medical care to sick or injured livestock, applying vaccinations and spraying insecticides on the open range, and assisting with the breeding, birthing, raising, weaning, castration, branding, and general care of livestock.” *Id.* The NPRM further proposed that any duties performed at the ranch or farm must either constitute the production of livestock or be closely and directly related to herding and/or the production of livestock, and that any such closely and directly related work must be minor, sporadic, and incidental. *Id.* Section 655.201 of the NPRM proposed to define “minor, sporadic, and incidental work” as “[w]ork duties and activities that are closely and directly related to herding and the production of livestock and are performed on no more than 20 percent of the workdays spent at the ranch in a work contract period.” *Id.*

Because the proposed definitions of herding, the production of livestock, and minor, sporadic, and incidental work operated together to define the scope of permissible job duties for a worker employed under these regulations, the commenters generally discussed them together; similarly, we are addressing them together. The Final Rule retains the definition of herding as proposed; modifies the definition of the production of livestock to include duties that are closely and directly related to herding or the production of livestock; and eliminates the 20 percent

cap on such closely and directly related duties. To provide further guidance, the Final Rule also includes examples of duties that qualify as closely and directly related and duties that do not qualify under these rules.

ii. Comments

A substantial number of commenters addressed the proposed intertwined definitions of permissible herder duties. Almost all of the commenters that addressed the proposed 20 percent cap were opposed to it. Some commenters expressed their opposition directly in commenting on the 20 percent cap, while others provided a more generalized opposition to the proposed definitions' limitations on permissible duties.

Mountain Plains and Western Range stated (in a comment adopted by numerous other commenters) that the proposed definitions “are inappropriately restrictive and are not a realistic reflection of the industry's labor needs.” They specifically stated that the 20 percent limit on days spent performing incidental work was “arbitrary” and “unworkable.” They suggested that the Department use “a more holistic and flexible approach” as in the regulations implementing the FLSA's minimum wage and overtime exemption for agricultural employees “principally engaged in the range production of livestock.” 29 U.S.C. 213(a)(6)(E). Those FLSA regulations look to whether the employee's “primary duty” is range work. 29 CFR 780.325(a). Under the FLSA, a worker “who spends more than 50 percent of his time” on the range performing range production duties is exempt from minimum wage and overtime. 29 CFR 780.325(b). Thus, under the FLSA, such an exempt “employee may perform some activities not directly related to the range production of livestock, such as putting up hay or constructing dams or digging irrigation ditches.” *Id.* The Mountain Plains and Western Range comment stated that we should similarly recognize that “other work has historically been connected to that work and must be included in the definition of the job.” They asserted that the NPRM did not explain how the 20 percent rule would help U.S. workers or how H-2A workers were harmed by its absence. They also asserted that the wording of the 20 percent cap on the number of days that could be spent on such incidental work was confusing, and they thought it might mean that only one day out of five at the ranch could be spent working and the other four spent had to be spent resting.

Cunningham Sheep Company and Dufurrena Sheep Company both commented that “[l]imits on incidental work related to herding would unnecessarily burden our operation” because “herders need to remain flexible and be able to perform husbandry-type jobs without unrealistically mandated rules.” Another sheep rancher stated that the definition of incidental work “needs to be more clearly defined and broadened. Fences need to be repaired to hold the sheep in, supplemental feed fed, and a host of associated jobs that do not necessitate the need for additional job descriptions and employees.” Another rancher asserted that, while “H-2A workers should not be diverted to work such as construction,” they should be permitted to perform “related livestock tending duties, such as the building of lambing jugs.” Etchart Livestock similarly stated that incidental work related to sheep production should be allowed, such as “[f]ence repair, corral repair, or other limited tasks,” but did not want a percentage cap; this commenter also stated that if the work does not involve sheep production, it should not be permitted. The Wyoming Farm Bureau Federation stated that the 20 percent “is too low a cap given the nature of the industry.”

Some comments revealed that the ranchers essentially want the workers to be able to perform any chore required (although a number of the examples they gave are animal husbandry duties that fall within the definitions of herding or the production of livestock). One sheep and cattle rancher, Kelly Sewell, noted that workers perform a variety of duties at the ranch base and thus wanted a general agricultural classification because these “valuable employees irrigate crops, fix fences, and many other jobs necessary to run a ranch.” Similarly, Indart Ranch stated that, in “addition to caring for the sheep and husbandry duties, our herders are constantly building and taking down fence, driving pickups and water trucks, fixing and maintaining equipment, amongst many other ranch type duties.” Another sheep rancher commented that, “[a]s long as the workers are working on the ranch . . . there should not be such a thing as a 50–20 rule.” The Rocky Mountain Sheep Marketing Association acknowledged that ranchers sometimes employ extra workers as insurance against an H-2A worker falling ill or going home due to a family need, and stated that under the current regulations “this extra help can be put to productive work on non-herding, necessary work on other aspects of the ranching

operation.” The Colorado Wool Growers Association commented that there are many chores associated with maintaining the herd, including “fixing a sheep pasture fence or irrigating a field that is grazed by sheep.” The Association suggested that such activities should not necessitate a separate job or pay rate, but rather that the permissible job duties should include all such chores. CLUB 20 also recommended expanding the job description “to include all chores that are in direct support of maintaining livestock managed in a grazing livestock production system.” Similarly, Mountain Plains and Western Range suggested replacing all of the definitions with a comprehensive “grazing livestock production system” definition.

A number of other comments contained the same theme—that the H-2A workers should be permitted to perform any duty at the ranch, including some activities that would constitute herding or the production of livestock and some that would not. For example, the John Espil Sheep Company comment noted that the livestock workers spend time at the ranch when weaning the calves before they are sold, and that feeding the calves may only take a couple of hours a day. Therefore, they also may perform other duties such as: repairing corrals or the feedlot fence; cleaning the shop, the bunkhouse and the tack room; and harvesting hay for winter feed. The company stated that this is all part of livestock production, and that keeping track of their time hourly or daily would be extremely difficult or impossible, both on the range and at the ranch, because every day is different. Similarly, another sheep rancher, Katie Day, commented that the workers irrigate pastures, harvest livestock feeds, maintain fences, clean corrals, doctor sheep and feed them, and it would be “absurd” to limit how long a job can be performed or to require recordkeeping for the incidental work. Finally, the Garfield County Farm Bureau similarly stated that “[w]hat is defined as incidental work is vital to the day-to-day operations of their ranches. Without the upkeep of fences, pasture irrigation, mitigation of noxious weeds and production of livestock feed, their operations cannot exist. As ranchers, they must be able to perform whatever job needs done at any given time and would expect their employees to do the same. . . . In short, there is no such thing as incidental work on a livestock ranch.”

Many employer commenters seemed to object to the 20 percent cap on directly and closely related duties while at the ranch based, at least in part, upon

their concerns regarding the associated recordkeeping requirements and, in some cases, a misunderstanding of those requirements. Those specific concerns are addressed in Sec. IV.B.2. of the preamble related to the recordkeeping provision in § 655.210(f).

Numerous employer commenters and their representatives, including American Sheep Industry Association (ASI), Mountain Plains and Western Range, California Wool Growers Association, Colorado Wool Growers Association, Texas Sheep & Goat Raisers Association, Vermillion Ranch and Midland Livestock Company, and John Espil Sheep Company, suggested that the Department adopt a much broader definition of permissible shepherd duties. They generally labeled their preferred definition as the “Grazing Livestock Management System.” That definition permits “the utilization of herbage or forage on a piece of land via grazing or supplementation” and turns inputs into goods (protein, wool, etc.) through practices that:

include but are not limited to: animal husbandry, temporary fencing, permanent fencing, management of urban interface, transport of water for animal use, use of structures and corrals to facilitate production practices, assistance with production of feed sources for animals being cared for, assistance with repair and maintenance of equipment and facilities used in production practices, trailing livestock and/or assistance in loading and unloading animals into livestock trucks for movement.

Mountain Plains and Western Range stated that this definition would make clear that feedlots and similar operations are not covered, while focusing on the critical component of the job—the grazing of livestock. In a joint comment, Vermillion Ranch and Midland Livestock Company (Vermillion and Midland) stated that it would be “general enough to encompass multiple open range occupations without creating arbitrary line-drawing that is impossible to follow.” They opined that this definition and the FLSA regulatory definitions would be “sufficient to protect the integrity of the special procedure regulations” while not replacing established occupational practices. The Wyoming Wool Growers Association stated that this definition would reflect that herding goes beyond just controlling animal movement and includes animal care and husbandry and natural resource management. The Association commented that the suggested definition of shepherd duties recognizes the totality of the process. Finally, the California Wool Growers Association stated that this definition would “more accurately

reflect current industry practices and requirements.”

In contrast to most employer commenters, Billie Siddoway, on behalf of the Siddoway Sheep Company, submitted a detailed description of the specific activities performed during various months of the year and did not object to the proposed 20 percent cap. Billie Siddoway stated that if an employee undertakes minor, sporadic or incidental work outside the definition of herding, such as by performing tasks as erecting temporary pens and corrals in anticipation of the lambing season, the employer could track those hours and job duties in order to allow the Department to evaluate compliance with the 20 percent rule. Billie Siddoway requested clarification that the 20 percent limitation applies only to work performed on the ranch (so that, for example, if a pair of workers divide up their chores on the range with one primarily responsible for tending the sheep and the other primarily responsible for caring for the camp and the dogs and horses, there is no need to evaluate that range time).

In further contrast to the vast majority of the employer comments, the Worker Advocates' Joint Comment agreed that the definitions of the terms “herding” and “livestock” are accurate, but stated with respect to the proposed definition of “minor, sporadic, and incidental work” that the 20 percent rule “is a critically important element of the proposed rule.” They emphasized that sheep herders have alleged in litigation that they often are assigned work outside the permissible duties and spend significant time performing duties such as irrigating fields, harvesting crops, and maintaining ranch buildings, vehicles, and equipment. Nonetheless, the workers have been paid the monthly wage required under the TEGL rather than the higher hourly AEWR, which could lead to displacement of domestic workers employed as ranch hands. The Worker Advocates' Joint Comment requested that the Department give more examples of work that would be minor, sporadic and incidental (repairing a fence or corral) as well as examples of work that falls outside the permissible job duties (e.g., constructing fences or corrals, reseeding, haying, operating and repairing heavy equipment, and constructing dams, wells, and irrigation ditches). They further suggested that the Department expressly prohibit such other work. As noted, the suggestions related to recordkeeping are discussed in Sec. IV.B.2. of the preamble with regard to § 655.210(f).

iii. Discussion

The NPRM recognized that employers using these procedures to hire workers for the range production of livestock may, at times, require the workers to bring the herd to the ranch or farm for certain periods to perform work that constitutes the production of livestock, such as lambing or calving, shearing, branding, culling livestock for sale, or tending to a sick animal. The NPRM further recognized that, during such periods at the ranch, the workers could also perform other work that is closely and directly related to herding or the production of livestock. The NPRM proposed to limit to 20 percent the number of ranch days that could be spent performing such directly and closely related work, and it required that the other directly and closely related ranch duties be included in the job order. See 80 FR at 20303.

The purpose of including the proposed 20 percent cap was to require that workers being paid the herding and range livestock wage not be used as general ranch hands, who are entitled to the standard H-2A hourly AEWR for all hours worked, because these provisions are only intended for workers who attend the herd as it grazes on the range. 80 FR at 20301. The Department determined that some limit on the scope of duties such workers could perform was essential because, in the course of its investigations, it found that some workers are stationed at the ranch for extended portions, if not all, of the job order and are performing general ranch hand work rather than work closely and directly related to the range production of livestock. Therefore, the NPRM identified tilling the soil for hay and constructing an irrigation ditch as examples of work not closely and directly related to herding or the production of livestock. The inspection and repair of the corral was given as an example of work that is closely and directly related. 80 FR at 20303, 20306.

After considering all the comments received, we have decided to remove the 20 percent limitation on the number of ranch days that can be spent on work that is closely and directly related to herding or the production of livestock, because such work is inextricably linked with those primary tasks. Where such work is, indeed, closely and directly related, it comprises an essential part of the work that employees who are engaged in herding and the production of livestock perform. Further, allowing workers to perform work that is closely and directly related to herding and the production of livestock on only one out of every five

days at the ranch unnecessarily limits the ranchers' flexibility in dividing tasks among their H-2A workers.

For example, herders may be at the ranch for two months during birthing season. During that time, the workers may remain responsible for caring for the dogs they use on the range to help herd and guard the sheep or goats; they also may remain responsible for the care of the horses they use on the range to pull their camps or to assist with herding. The proposed 20 percent cap on the number of ranch days that a worker could perform such closely and directly related work would have required the employer to divide the animal care sequentially among five herders, so no one worker performed it more than 20 percent of the days. The employer would have violated the cap if it instead had required that one herder do the animal care every day, even if the task only took one or two hours to perform. Smaller ranchers with fewer than five H-2A workers would have found it very difficult to comply with the proposed limitation on the percentage of days such work can be performed at the ranch. When the work is closely and directly related to herding or the production of livestock, there is no need to limit its performance in this way. Therefore, we are including closely and directly related work within the definition of the production of livestock, which provides employers with sufficient flexibility to assign appropriate tasks to workers when they are not on the range. The Final Rule makes conforming changes to delete references to the 20 percent cap in §§ 655.200(b)(1) and (2), 655.210(b), and 655.230(d).

However, we continue to conclude that it is inappropriate to provide employers with the unlimited latitude that some requested by allowing them to require workers employed pursuant to these rules to perform any ranch duties that are necessary to meet the day-to-day needs that arise in ranch operations. Accordingly, the Final Rule does not adopt the revised Grazing Livestock Management System definition of permissible duties, as recommended by a number of employers and their representatives. That definition is overly broad and vague, with undefined terms, such as “management of urban interface,” which make it unsuitable for the Final Rule. That definition would allow ranchers virtually unfettered discretion to assign workers any duties, unrelated to herding and the production of livestock, particularly because it states that the permissible duties “include, but are not limited to” the listed tasks. More specifically, under

that definition, workers could perform additional tasks such as assisting with the production of feed sources for animals being cared for, which could include planting crops like hay or alfalfa, irrigating the crops, applying pesticides to the crops, harvesting the crops, and drying and storing the crops. That definition also would allow workers to assist with the repair and maintenance of any equipment and facilities used in production practices, which could include work repairing a harvesting machine or maintaining a grain silo. The Department concludes that allowing such general ranch hand work to be performed by herding and range livestock workers, rather than by corresponding U.S. ranch hand workers who would earn the standard hourly AEWR, would have an adverse effect on U.S. workers similarly employed.

For similar reasons, the Department also is not adopting the FLSA's regulatory definition, as some commenters suggested. The FLSA regulation, 29 CFR 780.325, is tied to the FLSA's statutory language, which exempts an employee "principally engaged" in the range production of livestock. Therefore, that regulation allows a tolerance for non-herding work so long as it is less than 50 percent of the work hours. However, such a tolerance would be overbroad in the context of these H-2A rules, which create a special exception from the standard H-2A wage requirements.

Therefore, in order to fulfill our original purpose of providing that workers employed pursuant to the herding and range livestock regulations are not working as general ranch hands when they are not on the range, and to provide the requested guidance and clarity to both workers and the regulated community, the Final Rule includes several additional examples both of duties that qualify as directly and closely related to the production of livestock and duties that do not qualify. The Final Rule identifies the following as examples of work on the ranch that is closely and directly related: repairing fences used to contain the herd; assembling lambing jugs; cleaning out lambing jugs; feeding and caring for the dogs that the workers use on the range to assist with herding or guarding the flock; feeding and caring for the horses that the workers use on the range to help with herding or to move the sheep camps and supplies; and loading animals into livestock trucks for movement to the range or to market. Furthermore, we note that many of the duties that the commenters stated should be permissible (caring for sick animals at the ranch, providing

supplemental feed, and assisting with lambing) already are included within the definition of the production of livestock. The Final Rule identifies the following as work that is not closely and directly related: Working at feedlots; planting, irrigating and harvesting crops; operating or repairing heavy equipment; constructing wells or dams; digging irrigation ditches; applying weed control; cutting trees or chopping wood; constructing or repairing the bunkhouse or other ranch buildings; and delivering supplies from the ranch to the herders on the range. Several of these examples are taken from the FLSA regulations implementing the exemption for the range production of livestock, which a number of commenters identified as a model for this rule. See 29 CFR 780.325(b), 780.327, 780.329(c).

Further, the Final Rule provides employers adequate flexibility in the use of H-2A workers, while still requiring that the work be agricultural and herd-related in nature. Thus, although workers employed pursuant to the herding and range livestock provisions may not engage in work that falls outside the scope of these rules, the Department does not intend to debar an employer who in good faith has H-2A workers perform an insubstantial amount of herding work not listed in the Application. In exercising our enforcement discretion when an employer has had an H-2A worker perform work outside the scope of the activities listed on the job order due to unplanned and uncontrollable events, the Department will consider the employer's explanation, so long as the activities are within the scope of H-2A agriculture, have been occasional or sporadic, and the time spent in total is not substantial. Moreover, the debarment regulations require that the violation be substantial, and that a number of factors must be considered in making that determination, including: An employer's previous history of violations; the number of workers affected; the gravity of the violation; the employer's explanation, if any; its good faith; and its commitment to future compliance. Under these criteria, the good faith assignment of a worker to work not listed in the Application for a small amount of time would not result in debarment. The Department concludes that this improved clarity of the scope of the rules for herding and range livestock workers will lead to improved compliance and more effective enforcement by the Wage and Hour Division. As we explained in the NPRM, 80 FR at 20303, where

employers violate this limitation on duties, they may owe back wages and DOL may seek other relief depending upon the precise nature of the violation.

b. Definitions of Livestock and Range Housing

i. Livestock

Livestock is not defined in the TEGs. The NPRM defined livestock as "[a]n animal species or species group such as sheep, cattle, goats, horses, or other domestic hooved animals. In the context of this subpart, livestock refers to those species raised on the open range." 80 FR at 20339. As explained in the NPRM, the proposed definition of livestock described the type of animals, when managed on the range, covered by these rules. 80 FR at 20303-04. As mentioned above, Mountain Plains and Western Range suggested replacing all of the definitions with a "grazing livestock production system" definition, but this would not address the type of animals covered by these rules. The Worker Advocates' Joint Comment agreed that the definition of the term livestock is accurate. Because the Department received no comments opposing the proposed definition of livestock or otherwise suggesting modification, the Final Rule retains the proposed text without any modification.

ii. Range Housing¹²

The TEGs set standards for, but do not define, range housing. The NPRM defined "mobile housing" as "[h]ousing meeting the standards articulated under § 655.235 that can be moved from one area to another area on the open range" and explained that this definition "focuses on the movable nature of the housing used on the open range and specifies the provision in the regulation that sets forth the standards such housing must meet." 80 FR at 20304. The Worker Advocates' Joint Comment agreed with the NPRM definition of range housing. While the Department received comments regarding the standards for such housing and SWA inspection requirements, those comments are discussed in Sec. IV.E. of the preamble related to §§ 655.230 and 655.235. Because we received no comments opposing the definition of range housing or otherwise suggesting modification, the Final Rule reflects the definition proposed in the NPRM, with two modifications. First, we now refer to housing on the range as "range

¹² As noted in Sec. IV.E. of the preamble, and for the reasons discussed there, we have discontinued the use of the phrase, "mobile housing," and instead refer to housing on the range as "range housing."

housing” rather than “mobile housing,” as discussed further below in Sec. IV.E. Second, for the same reasons, we have deleted the requirement that the housing must be capable of moving from one area to another.

c. Definition of Range

i. Background

The TEGL for sheep and goat herding provides that the special procedures were established in recognition of the unique characteristics of sheepherding, which requires “spending extended periods of time grazing herds of sheep in isolated mountainous terrain; being on call to protect flocks from predators 24 hours a day, 7 days a week.” TEGL 32–10, ¶3. The TEGL provides that the SWA may rely on a standard job description of the duties to be performed and this description refers to “sheep and/or goat flock grazing on range or pasture,” but the terms “range” and “pasture” are not further defined. *Id.* at Attachment A, I(C)(1).

The TEGL for the open range production of livestock procedures similarly were established in recognition of the “unique characteristics of the open range production of livestock.” TEGL 15–06, Change 1, ¶3. The SWA may rely on a standard description of the job duties for a job opportunity in the open range livestock production industry, which refers to tasks performed “on the open range” and states that the workers also must “occasionally live and work independently or in small groups of workers in isolated areas for extended periods of time.” *Id.* at Attachment A, I(C)(1). No definition of “open range” is included in the TEGL.

The NPRM defined open range as “[u]nenclosed public or private land outside of cities and towns in which sheep, cattle, goats, horses, or other domestic hooved animals, by ownership, custom, license, lease, or permit, are allowed to graze and roam. Animals are not meaningfully enclosed where there are no fences or other barriers protecting them from predators or restricting their freedom of movement; rather a worker must actively herd the animals and direct their movement. Open range may include intermittent fencing or barriers to prevent or discourage animals from entering a particularly dangerous area. These types of barriers prevent access to dangers rather than containing the animals, and therefore supplement rather than replace the worker’s efforts.” 80 FR at 20339. The Department specifically sought comment on whether the definition of open range should

include a minimum acreage of the land on which the animals roam; under what circumstances (*e.g.*, state requirements related to the “open range”) the regulation may take into account barriers, fences, or other enclosures on this same land; and other factors that should be considered in the definition of open range. 80 FR at 20304.

The Final Rule removes the qualifier “open” and revises the proposed definition, using a multi-factor test based on a modified version of the definition of “range” used in the FLSA range production of livestock exemption. It sets forth the following factors that indicate the range: The land is uncultivated; it involves wide expanses of land, such as thousands of acres; it is located in remote, isolated areas; and range housing is typically required so that the herder can be close to the herd to fulfill the requirement to be constantly ready to attend to the herd. No one factor is controlling and the totality of the circumstances is determinative. The definition also specifies what is not considered range—specifically, that the range does not include feedlots, corrals, or any area where the stock would be near headquarters. The term also does not include any other areas where a herder is not required to constantly be available to attend to the livestock to perform tasks such as ensuring they do not stray off, protecting them from predators, and monitoring their health.

ii. Comments

The Department received a substantial number of comments addressing the proposed definition of open range. The comments addressed a number of issues, including: Fencing on the range; the changing nature of the landscape of the West and the feed used for sheep, including crop stubble; the necessity of herders regardless of fences and barriers; “open range” state laws; and the definition of “range” used in the FLSA range production exemption. The comments are addressed below according to the questions presented in the NPRM: (a) Whether the definition of open range should include a minimum acreage of the land on which the animals roam; (b) under what circumstances (*i.e.*, state requirements related to the “open range”) the regulation may take into account barriers, fences, or other enclosures on this same land; and (c) other factors that should be considered in the definition of open range. 80 FR at 20304.

(1) Comments on Minimum Acreage

The NPRM requested comments on whether the definition of open range

should include a minimum acreage of land. Mountain Plains and Western Range, along with a handful of other commenters, opposed a minimum acreage test. Mountain Plains and Western Range reasoned that an employer may not be aware of the acreage. Commenter Billie Siddoway supported modifying the definition to include “remote areas more than fifty miles from the base ranch that require delivery of water by truck.”

(2) Comments on Barriers, Fences, or Enclosures

Many commenters explained that livestock grazing varies substantially among operations, depending on the particular ranch owner and/or the geographic location. As indicated by the SBA Office of Advocacy, the practice of herding has changed since the 1950s and herders must graze on lands that are less “open.” Diamond Sheep Company explained that urban sprawl has changed herding patterns, as well as the availability and type of food consumed by sheep. Because the West is no longer an open area, sheepherding in its modern form has changed; according to the Idaho Wool Growers Association and other commenters, it increasingly includes “a mix of native grass on federal, state and/or private leases, hay and alfalfa grazing, crop aftermath grazing, feeding under power lines and in vineyards and even small parcels in residential areas for fuel load management.”

The comments almost unanimously opposed using fencing as a defining factor for “open range.” Commenters indicated that the prohibition on fencing was one of the two most problematic aspects of the NPRM. The comments explained that fencing is common on the range; Mountain Plains and Western Range stated that there is “no such place” that contains such unenclosed land as the Department had described in the NPRM. Stephany Wilkes stated that the idea that grazing only takes place away from fences is “unrealistic, magical thinking.” Mountain Plains conducted a survey of its members and of the 140 employer-members who responded, 45 percent of respondents indicated that their operation would not qualify as “open range” according to the definition in the NPRM. The opposition can generally be described as deriving from the realities of the modern landscape in the West where fences appear for many reasons, including on federal land managed by the Forest Service and the BLM, as well as the proposition that sheepherding requires a herder to be present regardless of whether the area has

fencing. Numerous ranchers explained that fences are necessary for a variety of reasons, including to mark boundaries, separate plant or animal species, protect crops or property, keep sheep from eating poisonous plants, manage grazing, protect animals from predators and keep them safe from traffic on public roads. They also stated fences are used for rangeland improvement, riparian or riverbank zones protection, and sustainability of rangelands.

The employer comments indicated that fencing may be used on both small and large acreages; the size of fenced land varies, and sheep may be within fences but within thousands of acres of private land. For example, Etchart Livestock, Inc. stated that its private pasture is fenced and varies in size from 4 acres to 4,000 acres. The Washington State Sheep Producers described large bands of sheep that are herded on unfenced open range from early spring to fall and are also herded across 500+ acre rangelands that are fenced for cattle containment, not sheep containment. Rangeland described by D.A. Harral was fenced around the exterior and broken up into 2,000 to 10,000 acre tracts of semi-arid land.

A common theme throughout the comments submitted by ranchers and their associations was that fencing does not replace the need for herders. Julie Hansmire expressed the view that regardless of whether a fence is a quarter of a mile from the sheep or 20 miles, a herder is still required. As explained in the comments, if a fenced area is very large, a herder may keep the sheep in a manageable area, and a herder also keeps the animals moving to graze on different areas for controlled grazing. For example, Hansen Ranch pointed out that its sheep are grazed on Forest Service land to control the noxious weed "Leafy Spurge," and the sheep herders are needed to keep the sheep grazing on this weed within a fenced area. Many commenters, such as John Parker and the Washington State Sheep Producers, pointed out that sheep cannot be left alone on the range because they may stray from the band of sheep and become lost, or be attacked by predators. Commenters also noted they used temporary fencing as well.

The employer commenters expressed particular concern about predators, explaining that sheep herders are critical to protecting sheep from attack regardless of whether the sheep are in a fenced area. As Pauline Inchauspe described, "[c]oyotes and mountain lions are a constant threat and though the herders are equipped with livestock guardian dogs, there is no substitute for the watchful eye of a shepherd. Their

24 hour presence is a necessity . . . throughout the entire year." For example, Detton Fawcett put a herd on private ground with fences and lost 40 percent of his herd over the summer; on another piece of land he lost multiple lambs (stating that losing 50 or more lambs in three weeks is common). Yet, with a herder present, Mr. Fawcett stated that he only loses approximately five percent of the herd.

Commenters also pointed out that the term "open range" refers to state laws that require property owners to build and maintain fences sufficient to keep livestock off their property. For example, William Ashby Maltsberger, a Texas rancher, submitted information on the Texas livestock laws explaining this concept. He pointed out that the NPRM definition of open range would prevent range producers of livestock, who are required by Texas open range law to fence their properties, from using the special procedures. Similarly, Tom Thompson explained that "[o]ur understanding of open range is that if you want to keep other people's livestock off your property you have to put up fences, making fences required in areas where there are other ranchers."

(3) Comments on Other Factors That Should Be Considered in the Definition of Range

(a) The FLSA Range Production Exemption

Both industry and worker advocates suggested using the FLSA range production of livestock exemption definitions in some form for the purposes of the H-2A rule, some suggesting adopting them in full and some emphasizing different portions. Mountain Plains and Western Range and the Worker Advocates' Joint Comment generally encouraged the Department to align the definition of "range" with the FLSA regulations, as discussed further below.

The FLSA range production of livestock exemption regulation defines the term "range" at 29 CFR 780.326(a) and (b). That regulation describes the range generally as land that is not cultivated and typically is not suitable for cultivation because it is rocky, thin, semiarid, or otherwise poor. It is land that produces native forage for animal consumption, and it includes land that is revegetated naturally or artificially to provide a forage cover that is managed like range vegetation. The range need not be open. The regulation provides that many acres of range land are required to graze one animal unit (five sheep or one cow) for 1 month; therefore, by its nature, the range

production of livestock is most typically conducted over wide expanses of land, such as thousands of acres.

The FLSA regulation at 29 CFR 780.329 provides that an employee is exempt if his primary duty is the range production of livestock and that this duty necessitates his constant attendance on the range, on a standby basis, for such periods of time so as to make the computation of hours worked extremely difficult. The fact that an employee generally returns to his place of residence at the end of each day does not affect the application of the exemption. However, exempt work must be performed away from the headquarters, which is the place for the transaction of the business of the ranch; the headquarters does not include large acreage, but only the ranchhouse, barns, sheds, pen, bunkhouse, cookhouse, and other buildings in the vicinity. The FLSA exemption does not apply to feed lots or to any area where the stock involved would be near headquarters. Rather, it applies only to those employees principally engaged in activities requiring constant attendance on a standby basis, away from headquarters, such as herding, where the computation of hours worked would be extremely difficult.

Although Mountain Plains and Western Range indicated a preference for eliminating an independent definition of range altogether and instead using the alternative "grazing livestock production system," (discussed more fully above with regard to the "production of livestock" definition) they alternatively recommended replacing the definition of open range in the NPRM with the FLSA definition of range. Specifically, Mountain Plains and Western Range stated that the use of the phrase "range" as defined in the FLSA is a better fit than "open range," as nothing is truly "open" land anymore.

The Worker Advocates' Joint Comment emphasized that the rule should specify that the land must be uncultivated so that the H-2A procedures for sheep herders are not more encompassing than the FLSA definition. The Worker Advocates' Joint Comment also supported using a worker's proximity to the ranch as an indication of whether the work is on the open range. Their comment stated that "ranch or farm signifies a place where crops are cultivated or where livestock are enclosed. Proximity to a location where livestock must be enclosed or where land is cultivated is an indication that such a place is not the open range." They suggested a slight modification to the FLSA definition, stating that work

activity performed “near a ranch or farm used by the employer” is not done on the range.

Other comments echoed similar elements about the topography of range or rangeland, which are factors found in the FLSA definition. For example, Lyle McNeal stated that range has native forages of grasses, forbs, and shrubs and that “range is also defined as uncultivated land, including forest land, which produces forage suitable for livestock grazing.” However, this rancher also noted that herders are needed on other types of land. McNeal further explained that the term “improved range” involves “reseeding and replacing the native range plants with a specific improved forage plant, *i.e.*, crested wheat grass, forage kochia, etc. Improved range might also refer to water developments, springs, or wells, including reservoirs or guzzlers.” Similarly, according to the sources attached to the comment submitted by Vermillion and Midland, “rangeland” is defined as “land on which the native vegetation (climax of natural potential) is predominantly grasses, grass-like plants, forbs, or shrubs suitable for grazing or browsing and present in sufficient quantity to justify sufficient grazing or browsing use, [including] non-native vegetation which was either planted for reclamation purposes or has since invaded the rangeland.” “Range” is defined by these sources as “an open region over which animals (as livestock) may roam and feed.”

(b) Crop Residue and Stubble

The ASI represented that 46 percent of their sheep spend part of the year on federal grazing permits or allotments, but noted that the availability of federal grazing land is on the decline and private grass, supplemental hay, and crop aftermath are the other available grazing options. The Idaho Wool Growers Association identified the primary times crop residue or stored crops (baled hay and corn) are used for feed is during the fall when the sheep are coming down off the mountain, in the winter when native food cannot be found, and in times of drought. The Washington State Sheep Producers indicated that the sheep graze for part of the year on crop aftermath in irrigated crop circles of 100–150 acres in size, and that herders are necessary to move the sheep among the crop circles. The Wyoming Livestock Board stated that “[m]any producers graze also on crop residue, private leases, vineyards and other parcels near fixed ranch sites and populated areas” and that these areas still require managed herding. Eph Jenson Livestock explained that they

have been desperate to find feed for the sheep and that allowing sheep to feed on crop residue is an economical means of clearing the field for the farmer. Cunningham Sheep Company stated that crop residue grazing is healthy for the sheep and the agricultural economy because it allows producers to remove residue without burning or using another destruction method.

The distance crop residue grazing takes place from the ranch, and from urban areas, may vary by operation and by geographic location. For example, numerous commenters, including the Utah Farm Bureau Association, the American Farm Bureau and the Sublette County Conservation District, noted that sheep are used for fire prevention close to urban areas, especially in California. Comments indicated that California’s sheep industry relies on crop residue grazing near urban areas anywhere from 6 months a year (Roswell Wool) to year-round (California Wool Growers Association). Elgorria Livestock characterized grazing on crop residue as a “large part” of the production cycle in California.

(c) Mobile Housing

Although not directly discussing the definition of “range,” many commenters, such as the Wyoming Wool Growers Association, noted that mobile housing is necessary for range work because it enables the herder to remain with the herd. As the Colorado Wool Growers Association explained, mobile housing is necessary because “livestock is often grazed far from the nearest town, or the ranch headquarters. It would be illegal to build fixed housing on U.S. Forest Service, Bureau of Land Management grazing allotments, as well as numerous other locations that livestock are grazing. It is not feasible to drive herders back and forth to work every day, leaving sheep unattended and vulnerable to predator attacks, straying too far from water sources, or being exposed to poisonous plants. While a lot of predator attacks happen at night, it is not unusual for predators to attack in broad daylight. This is why there has been the historic recognition of the necessity for mobile housing to keep herders near the sheep.” However, the Wyoming Farm Bureau Federation noted that many livestock workers do not need mobile housing for even 50 percent of the workdays in a contract. Further, as explained by Mountain Plains and Western Range, there are a limited number of employers who use stationary bunkhouses on the range rather than mobile housing at points throughout the “vast areas of land” where cattle are grazing, particularly in

Montana and Texas. Finally, the Worker Advocates’ Joint Comment indicated that requiring the use of mobile housing would have the unintended effect of inducing employers to house workers in mobile housing when fixed site housing is available; they stated that the nature and location of work should be the focus instead.

iii. Discussion

Based on the comments received, it is apparent that herding practices have evolved significantly over the last 50 years and the proposed definition of “open range” in the NPRM did not reflect these changes. The Final Rule, therefore, adopts a multi-factor test for defining what constitutes the “range.” As explained below, the Final Rule’s definition allows more flexibility than the NPRM and offers more guidance than the TEGLs by drawing on the FLSA regulatory definition suggested by many commenters as a starting point. The definition maintains a nexus to the longstanding purpose of the special procedures, to provide that herders can be available to tend to the flock in remote locations 24 hours a day, 7 days a week. In response to the information received in the comments, the Department will no longer use the term “open range,” will not use a set minimum number of acres in the definition of range, and will not use fencing as a defining feature of the range. We will, however, continue to consider the number of acres as a relevant factor in the determination of range. We address these considerations below.

First, the definition of “open range” in state law has limited use for the purposes of determining special procedures for herders, and the use of the term “open range” in these rules may cause unnecessary confusion in “open range” states. Therefore, as a result of the concerns raised by commenters, the Department no longer uses the NRPM phrase “open range,” and instead the Final Rule defines “range.”

Second, in response to comments, the Department has not included a minimum number of acres in the definition of range. However, the amount of acreage is relevant as a factor in determining whether the area is considered the range, as discussed further below.

Third, the Department understands and appreciates the serious concern raised by commenters regarding the use of fencing as a proxy for open range as proposed. The comments demonstrate that using the NPRM definition is untenable for many ranchers due to the

extensive presence of fencing across many of the lands used for grazing, including the fencing present on BLM and Forest Service lands. Therefore, the Department is eliminating fencing as an indicator of range. For similar reasons the Department also declines to adopt a test using the “enclosure of livestock” as the indicator of range, or, as proposed by the Worker Advocates’ Joint Comment, as an indicator of ranch.

Rather, based on the comments, when assessing whether the work takes place on the range or off of the range, the Department will consider the following factors that indicate the range: The land is uncultivated; it involves wide expanses of land, such as thousands of acres; it is located in remote, isolated areas; and range housing is typically required so that the herder can be close to the herd to fulfill the requirement to be constantly ready to attend to the herd. No one factor is controlling and the totality of the circumstances is determinative. The question of whether any area on the ranch (beyond the headquarters, discussed below) is considered on the range, and therefore counts toward the 50 percent threshold requirement, or off of the range must be determined by looking at the factors established in this Final Rule. It is worth noting that when we use the term “ranch” as distinguished from the “range” in this Final Rule, we are referring to that portion of the ranch that does not qualify as range after analyzing it under the multi-factor test.

The range specifically does *not* include feedlots, corrals, or any area where the stock would be near headquarters, which is consistent with the FLSA range production of livestock exemption. The term also does not include any other areas where a herder is not required to constantly be available to attend to the livestock to perform tasks such as ensuring they do not stray off, protecting them from predators, and monitoring their health.

The work must be performed away from the headquarters used by the employer to qualify as range work. The term “ranch” is distinct from the term “headquarters.” The term headquarters is limited and does not embrace large acreage. The headquarters is the place where the business of the ranch occurs and is often where the owner resides. The term headquarters only includes the ranchhouse, barns, sheds, pen, bunkhouse, cookhouse, and other buildings in the vicinity, meaning that anything beyond this immediate area is not considered the headquarters. Any work performed at or near the headquarters would not qualify as work on the range for purposes of the

requirement for herders to spend more than 50 percent of their time on the range.

The Department maintains the requirement that the work must be done away from the headquarters in order to preserve the longstanding purpose of the special procedures—that the unique occupational characteristics require workers to spend extended periods of time in isolated, mountainous, remote areas to be available to attend to the herd’s needs on a 24/7 basis, making tracking of the hours worked exceedingly difficult. This situation does not exist when workers are stationed, for example, in a cultivated field *near the headquarters* where hours could be easily tracked (and where U.S. workers may be more interested in working). This fundamental historical purpose of the special procedures, and DOL’s statutory obligation to certify that there are not sufficient U.S. workers who are able, willing, and qualified to perform herding jobs on the range, require the Department to maintain geographic parameters for range work. For this reason the Department cannot allow for use of the Mountain Plains and Western Range definition of “grazing livestock production system,” because it does not account for the location where the work occurs.

Although the FLSA definition of range provides a useful starting point, the Final Rule does not fully adopt the FLSA definition of range in three key respects. First, for the reasons identified by the Colorado Wool Growers Association and other commenters, range housing typically is necessary for the workers covered under this Rule. The Final Rule contemplates that range housing is almost always a requirement of range work because the workers must be on call 24 hours, 7 days a week to tend to the needs of the animals, and range work cannot take place near the headquarters. Housing with the herd and away from the headquarters is therefore essential. However, the Department does not intend to provide an incentive to use range housing when it is not appropriate, as noted by the Worker Advocates’ Joint Comment. Further, the Department acknowledges the comments received about a small subset of workers who use a series of remote, stationary bunkhouses on the range while traveling with the herd, while it is grazing over vast areas of land; this practice would not disqualify their employers from using these regulations.

The second modification from the FLSA definition is for grazing that occurs on crop residue. Many of the descriptions of the land used for

herding submitted by commenters would easily fall within the FLSA range production exemption’s regulatory definition of the range as generally uncultivated land and land not suitable for cultivation; however, areas where sheep are grazing on crop residue may not always qualify as “range” under the FLSA definition. Therefore, to accommodate the comments that many sheep are feeding on crop residue during certain months of the year, often on leased lands at a distance from the rancher’s property as the herd trails to or from BLM or Forest Service allotments, the Department is establishing the multi-factor test, as well as excluding the FLSA regulation’s language, “land that is not suitable for cultivation because it is rocky, thin, semiarid, or otherwise poor.” 29 CFR 780.326(b). Allowing for some work on cultivated land, depending on the other factors, is consistent with the purpose of this variance (that the work is unique because it is remote and requires 24/7 availability, which makes the hours difficult to calculate) from the standard H-2A rules. The modern reality of herding, which the commenters indicate occurs on crop residue during certain seasons, does not necessarily disqualify herders who are operating remotely from the ranchers. However, we note that the FLSA regulation provides that “generally” the land is not cultivated and “typically” is not suitable for cultivation; therefore, the deletion of the language is not a significant modification, as the Final Rule still asks whether the land actually is cultivated as an indicator of the range. The Department recognizes that, depending on an analysis of the factors, the test established in the Final Rule may in certain cases encompass more land as “range” than under the FLSA, as indicated in the Worker Advocates’ Joint Comment. Additionally, in other cases, an area considered range under the FLSA may not be considered range under the test set forth in the Final Rule, depending on an analysis of the factors.

Third, the Department is intentionally omitting the sentence in the FLSA regulation stating that “[t]he balance of the ‘headquarters ranch’ would be the ‘range.’” 29 CFR 780.329(b). As discussed above, determining which portions of the balance of the ranch that is away from headquarters are considered on the range, and therefore count toward the 50 percent threshold requirement, or off the range will be assessed using the multi-factor test set forth in the Final Rule.

B. Pre-Filing Procedures

The Final Rule establishes pre-filing procedures for employers seeking workers to engage in sheep, goat and cattle herding jobs. These provisions assist employers in understanding their pre-filing obligations.

1. Section 655.205—Herding and Range Livestock Job Orders

The two TEGLs do not provide a variance from the standard rules for Form ETA-790 filing time frame or location, with one exception. Therefore, under the TEGLs, the standard Form ETA-790 filing requirements in 20 CFR 655.121(a) through (d) apply, except where an agricultural association submits a Form ETA-790 for a “master” job order (*i.e.*, a Form ETA-790 submitted by agricultural association as a joint employer with its employer-members) for range sheep or goat herder positions. Although, under the TEGLs, all Forms ETA-790 for standard H-2A job orders must be submitted to the appropriate SWA no more than 75 calendar days and no less than 60 calendar days from the employer’s start date of need, the TEGL applicable to sheep and goat herding employment permits a Form ETA-790 for a “master” job order for range sheep or goat herder positions to be submitted directly to the National Processing Center (NPC) once annually.

In the NPRM, the Department proposed variances from the job order filing requirements in 20 CFR 655.121(a) through (d) for all range herding and livestock production job orders. Specifically, the NPRM proposed requiring an eligible employer to submit the, *Agricultural and Food Processing Clearance Order*, Form ETA-790, directly to the NPC, rather than to the SWA. As proposed, the employer would submit the Form ETA-790 to the NPC at the same time it submits its *H-2A Application for Temporary Employment Certification*, Form ETA-9142A, as outlined in 20 CFR 655.130 (as modified by § 655.215 of the NPRM). Also as proposed, an employer submitting its labor certification application electronically using the iCERT Visa Portal System would be required to scan and upload the Form ETA-790 as well as all other supporting documents. The NPRM addressed the TEGL’s “master” job order annual Form ETA-790 submission allowance, available to associations filing master applications for sheep or goat herding or production occupations, in the proposed provision about variances from filing procedures at § 655.215.

The Department did not receive comments addressing the job order filing requirements proposed in § 655.205, and we therefore adopt the proposed § 655.205, with one minor change. As proposed and adopted, this provision essentially requires that all employers, whether filing as an individual, an association, or an H-2A Labor Contractor (H-2ALC), submit Form ETA-790, directly to NPC together with a completed *H-2A Application for Temporary Employment Certification*, Form ETA-9142A. As we explained in the NPRM, processing of these applications will be improved if we establish consistent filing requirements for employment of all herders in range herding and livestock production occupations. Allowing employers to file the Form ETA-790 with the NPC at the same time as the *H-2A Application for Temporary Employment Certification*, Form ETA-9142A, as proposed, will streamline the application process for both the filers and the agency. The only change we have made to the regulatory text of this provision is the deletion of the phrase “as required in § 655.130[.]” which is a reference to the standard H-2A regulations. We conclude that it is more helpful to the regulated public to substitute, “as required in § 655.215[.]” which is a reference to the applicable herding and range livestock filing requirements.

2. Section 655.210—Contents of Herding and Range Livestock Job Orders

Provisions in § 655.210 establish certain content requirements for job orders covering the employment of all herders in range herding and livestock production occupations. Section 655.210(a) reminds employers that if a requirement of the standard H-2A regulations is not addressed in the herding and range livestock regulations (such as workers’ compensation, among other requirements), then employer-applicants must comply with the standard regulation. We did not receive any comments from the public on this provision and are adopting it unchanged from the NPRM.

a. Section 655.210(b)—Job Qualifications and Requirements

Section 655.210(b) establishes the standards associated with job qualifications and requirements included in the job offer. Many of the standards contained in this provision have been addressed above, in Sec. IV.A.2., related to the nature of herding and range livestock jobs, and in Sec. IV.A.3., related to definitions. As a result, for the reasons discussed above in Sec. IV.A.2., we are adopting the

standard unchanged from the NPRM that the job offer must include a statement that the hours of work are “on call for up to 24 hours per day, 7 days per week.” In addition, for the reasons discussed in the same section above (Sec. IV.A.2.), we are clarifying the proposed standard that workers must spend “at least” 50 percent of their workdays during the contract period on the range. Instead, under the Final Rule, the job offer must reflect that workers spend a majority, meaning more than 50 percent, of the workdays during the contract period on the range. Finally, for the reasons discussed above in Sec. IV.A.3. related to definitions, we have decided to eliminate the 20 percent limitation on the number of ranch days that can be spent on work that is closely and directly related to herding or the production of livestock, because such work is inextricably linked with those primary tasks. Where such work is, indeed, closely and directly related, it comprises an essential part of the work that employees who are engaged in herding and the production of livestock perform. The Final Rule requires that all such duties must be specifically disclosed on the job order.

i. Background

Apart from the issues discussed in the paragraph immediately above and in the prior preamble sections referenced in that paragraph, several issues related to job qualifications and requirements contained in § 655.210(b), including worker experience requirements, are addressed here. Under the H-2A program generally, including under the TEGLs for sheep and goat herding and the range production of livestock, “job offers may not impose on U.S. workers any restrictions or obligations that will not be imposed on the employer’s H-2A workers.” 29 CFR 655.122(a). Additionally, each qualification and requirement included in the job offer must be “bona fide and consistent with the normal and accepted qualifications” required by employers not using H-2A workers for those occupations, and the Certifying Officer or the SWA may require supporting documentation to substantiate the appropriateness of any job qualification specified in the job order. 29 CFR 655.122(b).

The TEGLs provide additional information regarding permissible duties, qualifications and requirements. Both TEGLs mandate that the Forms ETA-790 submitted to the SWA provide descriptions of required job duties. TEGL 32-10, Attachment A, I(C)(1); TEGL 15-06, Change 1, Attachment A, I(C)(1). The TEGLs provide that any additional job duties “must be normal

and accepted for the occupation” and that the SWA and NPC have the authority to request supporting documentation to substantiate the appropriateness of any the duties. *Id.* The TEGs also provide that, “due to the unique nature of the work to be performed,” the job offer may specify that applicants possess up to 6 months of experience in similar occupations to shepherding or the range tending or production of livestock (as appropriate to the specific TEG) and employers may require reference(s) to verify such experience. *Id.* Applicants must provide the name, address and telephone number of any employer used as a reference. *Id.* Both TEGs note that the “appropriateness of any other experience requirement must be substantiated by the employer and approved by the Chicago NPC.” *Id.*

The NPRM similarly provided that the “job offer may also specify that applicants possess up to 6 months of experience in similar occupations involving the herding or production of livestock on the open range and require reference(s) for the employer to verify applicant experience.” 80 FR at 20339. The NPRM further proposed that an employer may specify other appropriate job qualifications and requirements. *Id.* The preamble to the NPRM explained that these qualifications “could include the ability to ride a horse, use a gun for occupational safety to protect the livestock herd from predators, or operate certain motorized vehicles.” 80 FR at 20304. The NPRM also specified that any qualification or requirement listed in the job offer must be bona fide, and that the Certifying Officer may require the employer to submit supporting documentation. 80 FR at 20339–20340. The NPRM further provided that any such qualifications or requirements must be applied equally to U.S. and H–2A workers, in order to maintain compliance with the prohibition against preferential treatment of foreign workers under the H–2A program. 80 FR 20304. As discussed further below, the Final Rule retains these provisions.

ii. Comments

The Department received very few comments directly addressing these provisions. Mountain Plains and Western Range commented that “the job qualifications continue over from the TEGs and are essential for identifying and hiring workers who possess the requisite skills for this special work.” As they explained, “it would be a disaster” to send a new worker to the range with a herd only to have that worker decide they do not in fact enjoy

the work or they do not know how to care for and protect the animals. Vermillion and Midland stated that “[e]stablished job descriptions and requirements for various open range livestock occupations should be deemed ‘bona fide’ and ‘appropriate’ under [these provisions] and should not be questioned.”

Although not addressing this provision directly, several commenters discussed the need for skilled herders and the length of time needed to become skilled in this work. For example, Rocky Mountain Sheep Marketing Association commented that their shepherds must be able to manage guard dogs and sheep dogs, horses, and, often, pack mules, “have a thorough grasp of basic veterinary medicine,” and must have the “skills and maturity to protect themselves in remote landscapes,” in addition to many other skills. They further commented that skilled herding is “essential for modern range management.” Peter and Beth Swanson commented that fencing must be done correctly to protect the herd; they stated that herders know what fencing is needed, and how to troubleshoot and correct problems. Mantle Ranch explained that their workers “know how the livestock is handled and where the livestock belong at any given time” and they are “capable of moving, containing, [and] watching over [the herd] for predatory problems, sickness” and the general welfare of the animals. Mantle Ranch further noted that there are many miles of fence and watering facilities that must be “continually monitored, repaired, and updated.” Kelly Ingalls, a sheep ranch manager, stated that “[m]ore animals are saved because of the [H–2A] herder’s experience in healing sick and injured animals.”

John & Carolyn Espil stated that “[a] master of sheep husbandry generally has years of experience and an exceptional aptitude for his work.” The Texas Sheep and Goat Raisers’ Association similarly commented that it takes years to adequately train a worker, and loss of a seasoned employee could set a business back. Hilger Hereford Ranch commented that a herder with only six months of experience may not understand or be experienced in all of the skills needed, as different tasks and skills are needed throughout the year.

In contrast, the Worker Advocates’ Joint Comment opposed the provisions allowing employers to require up to six months of experience and references to verify this experience. They stated that “the experience requirement often serves more as an exclusionary mechanism” rather than a “legitimate job qualification.” As they explained,

“experience requirements are often used as a barrier to exclude U.S. workers who may be qualified but do not have experience working with the particular [animal].” Additionally, the “‘verifiable’ experience requirement is an undue burden on U.S. workers, as employers often require an official reference on the company letterhead of the former employer.” As they explained, “migrant workers often do not maintain records of whom they worked for in the past” and may not have the names, locations or up-to-date contact information for those employers. Furthermore, they stated that verifiable experience requirements are not equally imposed on H–2A foreign workers. Similarly, Brian Clark commented that requiring six months of experience is unnecessary. Mr. Clark stated that three months of experience should be sufficient and that qualified U.S. workers could be found with three months of experience. Additionally, he noted that employers could allow for training in lieu of experience.

iii. Discussion

As set out in the TEGs, the provision allowing job offers to require up to six months of experience and verifiable references is due to the unique nature of the work to be performed, which often involves working alone for extended periods of time in remote locations where the herder is responsible for the safety of a herd, which the comments indicate is typically made up of approximately 1,000 ewes. The comments received on the NPRM demonstrate that these occupations require workers with experience in these jobs and the skills necessary to protect the animals and themselves. As explained in the preamble to the NPRM, these skills may include the ability to ride a horse, use a gun to protect the herd from predators, or operate certain motorized vehicles. As noted by Western Range and Mountain Plains, given the remote and unique nature of the work, it would be untenable to hire a worker with little to no occupational experience, who may decide quickly that this work is unsuitable or realize that he or she is unprepared to care for the animals. Additionally, as noted by several commenters, for the safety of the animals and the worker, it is important that workers be able to protect the animals and themselves while on the range. Therefore, the Final Rule retains the provisions from the NPRM allowing job offers to specify that applicants must possess up to six months of experience in similar occupations involving herding or range livestock production,

and require reference(s) for the employer to verify such experience.

The Department concludes that “up to six months” is a reasonable and appropriate limitation on the experience requirement. The six-month experience requirement is a longstanding requirement from the TEGLs, based on the unique characteristics of these occupations. As demonstrated by the comments, herding and range livestock production involve changing conditions throughout the year depending on grazing location, weather, predators, animal health, and other evolving circumstances. As these conditions change, different skills may be necessary, as noted by Hilger Hereford Ranch. For some employers, requiring workers to possess up to six months of experience in these occupations is reasonable, as a worker with less experience may have only encountered certain, limited range conditions and may be unprepared for different grazing locations, predator concerns, and weather conditions. Some commenters noted that it may take years of experience to become a skilled herder. The Department concludes that a maximum of six months of experience in similar occupations involving herding or production of livestock on the range, in light of the changing needs and conditions throughout the year, is a normal and accepted job requirement for these unique occupations to ensure that workers are sufficiently experienced in these unique occupations, while preventing unduly burdensome experience requirements that may prevent otherwise qualified U.S. workers from obtaining these positions. However, as underscored by the Worker Advocates’ Joint Comment, experience and qualifications requirements must be bona fide and equally required of U.S. and foreign workers. For example, if an employer requires less than six months experience of U.S. workers (for example, three months of experience), at least the same experience requirement must be required of foreign applicants.

Additionally, while employers may require “reference(s) for the employer to verify applicant experience,” such reference requirements must be reasonable and may not be used as a barrier to hiring U.S. workers. Requiring the type of formal, written reference on employer letterhead, as described by the Worker Advocates’ Joint Comment, is inappropriate under the Final Rule. Employers who want to verify previous employment must make reasonable efforts to locate and contact the previous employer where an applicant provides basic information such as that required

under the TEGLs—the prior employer’s name, address and telephone number—or similar information facilitating contact, such as an email address, or social media account. As noted above, any reference requirements for U.S. workers must be no more stringent than those imposed on foreign workers.

b. Section 655.210(c)—Range Housing

i. Background

The TEGLs required the inclusion of several statements in a job order about the unique aspects of range herder employment, including housing. The TEGLs set forth specific requirements, including an employer’s obligation to provide mobile housing for range workers.

In the NPRM, the Department proposed that the employer disclose in the job order seeking workers for range herding positions that mobile housing would be used to satisfy the employer’s housing obligation under 20 CFR 655.122(d) (requiring an employer to provide sufficient housing to workers, at no cost to the workers, where their work does not allow them to reasonably return to their residence within the same day). As proposed, the job order would state that mobile housing, meeting the requirements of §§ 655.230 and 655.235, would be provided to workers.

ii. Comments and Discussion

The Department only received a few comments applicable to this requirement. The comments from Mountain Plains and Western Range discussed the use by some employers of fixed-structures in remote areas to temporarily house range workers as they move a herd along its grazing trail. These comments are addressed below in connection with section 655.230. As discussed further in Sec. IV.E. with regard to range housing, the Department’s use of the term “mobile housing” was intended to distinguish between permanent, fixed-site housing subject to the standards in 20 CFR 655.122(d) standards and the temporary housing provided workers in different locations, usually in remote areas, as their herds move from one grazing area to another, and does not to preclude the use of alternative housing structures for range workers. The Department has modified the regulation in the Final Rule to enable an employer to accurately indicate the nature of the housing in the job order.

The Department, however, received numerous comments on the use of mobile housing, inspection requirements for such housing, and

minimum standards for the mobile housing, including those relating to heating, lighting, cooking, sleeping and personal hygiene while occupying such housing and the provision of food, water, and waste removal to workers while using mobile housing. These comments are discussed below in Sec. IV.E. of the preamble in connection with §§ 655.230 and 655.235.

c. Section 655.210(d)—Employer Provided Items

i. Background

All H–2A employers, including employers currently utilizing the TEGLs for sheep, goat and cattle herding, must provide to their workers, free of charge, all tools, supplies and equipment required to perform their assigned duties. 20 CFR 655.122(f). The TEGLs further specify that, due to the remote and unique nature of the work to be performed, employers must “specify in the job order and provide at no cost to workers an effective means of communicating with persons capable of responding to the worker’s needs in case of emergency.” TEGL 32–10, Attachment A, C(4); TEGL 15–06, Change 1, Attachment A, C(4). As recognized by the TEGLs, communication means are necessary to perform the work and can include, but are not limited to, satellite phones, cell phones, wireless devices, radio transmitters, or other types of electronic communication systems. Except for those requirements that relate to mobile housing standards, the TEGLs do not identify any additional tools, supplies or equipment that must be provided by the employer under 20 CFR 655.122(f).

The NPRM proposed that employers must provide to workers, without charge, all tools, supplies and equipment that are required by law, the employer, or the nature of the work to perform the job safely and effectively. 80 FR at 20340. The NPRM also proposed that employers must disclose in the job order which items it will provide to the worker. *Id.* The NPRM preamble explained that the required tools, supplies, and equipment will depend on a number of factors, such as the terrain, weather, or size of the herd, and provided a number of examples of such items, such as binoculars to monitor the herd, a gun to protect the herd and the herder, boots, rain gear, and a horse. 80 FR at 20305. The NPRM also noted that, as provided in proposed § 655.235 regarding mobile housing standards, protective clothing and bedding may be provided as an alternative to heating equipment in certain conditions, and this alternative

bedding and clothing is required by the job and must be provided free of charge or deposit charge. *Id.* The Department invited comments on other tools, supplies and equipment that may be required and whether it would be helpful to include in the regulation a list of items typically required by law or the nature of the work.

The Department also proposed requiring employers to provide workers, at no cost, an effective means of communicating with persons capable of responding to worker's needs in case of an emergency. 80 FR at 20304–20305. The NPRM provided the same non-exclusive list of acceptable communication devices as in the TEGs. 80 FR at 20305. Accordingly, the proposed provisions in § 655.210(d) would require employers to specify in the job order the electronic communication devices that will be provided to workers. *Id.* However, the Department also noted that a worker's location may be so remote that electronic communication devices may not operate effectively at all times. *Id.* To address this concern, the Department proposed to require that employers arrange for workers to be located in geographic areas where electronic communication devices can operate effectively on a regular basis, unless the employer will make contact in-person with the worker regularly. *Id.* The Department noted that the definition of "regularly" could vary, but a worker must be able to communicate with the employer at intervals appropriate for monitoring the health and safety of the worker. *Id.* We explained in the NPRM that such contact is in the best interest of both the employer and the worker in the event that there are problems with the herd, the worker suffered a medical emergency, or the worker's safety is threatened. *Id.* Last, the proposed provision also would require employers to include a statement in the job order specifying that it will make contact with the worker in-person or using electronic communication devices regularly. *Id.*

Based on the comments received, which we discuss below, the Final Rule retains the NPRM provisions requiring employers to provide, free of charge or deposit charge, all required tools, supplies and equipment and to disclose which items will be provided in the job order, but does not include a list of typically required items in the regulatory text. The Final Rule maintains the requirements that employers must disclose and provide to workers, free of charge or deposit charge, an effective means of communicating with persons capable of responding to the worker's needs in case

of an emergency, including, but not limited to, satellite phones, cell phones, wireless devices, radio transmitters, or other types of electronic communication systems. The Final Rule also revises § 655.210(d) to address situations in which workers are stationed in locations where electronic communication devices will not operate effectively. In such cases, the employers must either make arrangements for workers to be located in geographic areas where electronic communication devices can operate effectively on a regular basis, or provide for regular, pre-scheduled, in-person contact. The Final Rule also revises job order disclosure provisions to require the employer to specify the means and frequency with which the employer plans to make contact with the worker when the workers are stationed in locations where electronic communication devices may not operate effectively. Finally, the Department has divided subsection 655.210(d) in the Final Rule into two paragraphs, the first addressing tools, supplies, and equipment generally, and the second specifically addressing communication. We will address each topic separately below.

ii. Communication Devices

(1) Comments

The Department received a number of comments about the proposal to require employers to provide electronic communication devices to range herders and livestock production workers free of charge or deposit charge. The Worker Advocates' Joint Comment and the Western Watershed Project expressed concern that range herders and livestock production workers often work in remote locations with no means of communication in case of emergency. Western Watershed Project specifically noted that workers are exposed to various hazards in these remote locations, including exposure to disease and attacks from predators. Some employers, and employer associations Mountain Plains and Western Range, also agreed that electronic communication devices can help employers monitor the health and well-being of workers and the herd. One private citizen also suggested that workers should have access to a computer with Skype or similar communication that would allow the workers to contact a trusted person who speaks the workers' language. At least one employer also expressed concern about language barriers.

Only one comment, submitted by the Office of the Governor of Utah, urged the Department to eliminate the

requirement that employers provide an electronic form of communication, stating that the Department failed to provide adequate justification for the requirement and asserting that the requirement would create an excessive encumbrance on employers. This comment also suggested that, because "there is no apparent history of safety incidence to cause alarm," the Department should allow employers to develop their own action plans to provide means of communication to workers during emergencies. Other comments from employers noted that workers often use their employer-provided cell phones to contact their families abroad and suggested that workers should be responsible for the cost of such calls, as well as the cost of providing different devices that the workers may choose that are beyond what is necessary to effectuate emergency contact with the employer and emergency first responders.

We also received comments about workers' access to satellite phones. A comment from the Western Watershed Project urged the Department to require employers to provide workers access to satellite phones where in-person or cell phone contact is not available, as well as working batteries or rechargeable batteries and a solar charger to power the device for the amount of time spent in areas with limited or non-existent communication. This commenter also suggested that employers be required to maintain subscriptions for messaging services in cases of emergency and to provide proof of satellite coverage and appropriate equipment with respect to each worker on an annual basis. Some employer commenters indicated that they currently provide satellite phones to their workers for communication in geographic areas where there is no cellular service coverage and believed this was an effective way of providing contact in the event of an emergency.

The Worker Advocates' Joint Comment urged the Department to require employers to provide workers with a satellite phone for communication at all times. They suggested that, without access to satellite phones, workers who are out on the range with no cellular service coverage will have to depend solely on more frequent contact with the employer as the only means of obtaining aid in the event of an emergency, and that in-person contact with the employer, unless it occurs daily, is not a reliable way of providing access to assistance in cases of emergency. They also stated that the Department's proposal creates a potential conflict of interest for employers in responding to

worker emergencies because workers' compensation is triggered in the event of a work-related injury, and the comment alleged that many workers who have reported such injuries have been denied medical care by their employers. This comment, however, also acknowledged several alternatives to requiring employers to provide satellite phones. According to the Worker Advocates' Joint Comment, the Department could also give employers the option of providing workers with a mobile phone for everyday use and a satellite phone for times when the workers are out of cell phone service range. The Worker Advocates' Joint Comment further suggested, as a potentially inexpensive alternative to providing workers a satellite phone for everyday use, that employers could station workers in pairs while in areas with unreliable or no cell phone service. They indicated that because there are usually two herders working during the winter season, employers would only incur the cost of a second worker during the summer months on the range. They noted that while this arrangement would be less advantageous than having direct access to emergency responders via a satellite phone, the presence of a second worker would ultimately benefit both the workers and the employer by allowing workers to locate emergency service sooner while providing for continued care of the livestock in the interim.

Comments received from employers and employer associations reflected general agreement that a satellite phone is not an adequate substitute for in-person communication between employers and their workers, and urged the Department to adopt a flexible approach in the Final Rule. Mountain Plains and Western Range acknowledged that electronic communication devices can help employers track the health and well-being of workers, but noted that electronic communication cannot replace face-to-face communication. One employer stated that he had successfully used satellite phones as an effective alternative means of communicating with workers outside cellular service coverage areas, but stressed that employers should be allowed to find solutions that best serve their needs. Other commenters expressed concern about the cost of providing satellite phones and service plans, and one commenter reported that satellite phone service plans would cost \$300 to \$2,000 per year.

The Department received comments, from workers and employers, agreeing that employers should be required to

establish work locations where electronic communication devices will work effectively so that workers' safety and health can be monitored. One commenter stated that it was critical for employers to establish locations where a cell phone, satellite phone, or other device will work, or where workers can stop at a nearby ranch in the event of an emergency. Some employers indicated that they already provide their workers with cell phones with consistent coverage in the areas where workers are stationed, and that they intentionally station workers, as much as possible, in areas that provide cell phone coverage, allowing the workers to regularly contact the employer, as well as family and friends abroad.

The Department also received comments about minimum allowable intervals between contacts initiated by the employer. One commenter, a private citizen, expressed concern that in some cases, it may be over a month before workers have contact with their employer. Comments from Mountain Plains, Western Range, and other trade associations stated that establishing minimum intervals for employer-employee contact is unnecessary and infeasible given the unpredictable nature of the terrain, weather, and cellular telephone signals, and employers currently strive to maintain regular communication with their workers. Several employers pointed out that they have every economic incentive for maintaining regular contact with their workers because they are concerned with both the welfare of the workers and the welfare of the livestock. Other employers commented that they currently have practices in place that provide for regular contact with their workers, including three employers who reported maintaining contact with workers by designating "camp tenders," who are responsible for resupplying workers' camps and monitoring the health and the well-being of workers and the herd. One employer suggested that employer-employee contact every two to three days should be sufficient. Another employer suggested that as long as workers have the ability to contact the employer at any time, employer initiated contact every ten days is reasonable and sufficient. The employer further explained that some employers arrange for workers to work in pairs during the summer when the workers are in remote areas, and in such cases the employer may only have in-person contact with one of the workers in the working pair. They suggested that, to the extent that minimum contacts are imposed, contact with one member of

the working pair of employees in such arrangements should be sufficient. The Worker Advocates' Joint Comment suggested that in-person contact could not be relied upon for emergency purposes unless it is daily. They also stated that, for purposes of defining a reasonable amount of time between in-person visits to deliver necessities (e.g., food and water, hygiene products, first aid supplies, and clothing), workers should not go more than seven days without in-person contact with the employer.

The Worker Advocates' Joint Comment also emphasized that because workers must rely on their employers for delivery of mail, the Department should promulgate a rule prohibiting employers from opening workers' mail. They also reported that employers sometimes deny workers access to healthcare professionals, and prohibit workers from allowing visitors, using a radio, and possessing reading materials.

(2) Discussion

Based on the comments received, the Department has decided to maintain the proposed requirement, now located in § 655.210(d)(2), that employers must provide to their workers, free of charge or deposit charge, an effective means of communicating with persons capable of responding to the worker's needs in case of an emergency, including, but not limited to, satellite phones, cell phones, wireless devices, radio transmitters, or other types of electronic communication systems. We found overwhelming agreement among the commenters that this requirement is needed due to the isolated nature of sheep, goat and cattle herding on the range. As the Western Watershed Project comment accurately noted, workers in these occupations often work in remote locations without sufficient access to medical facilities or means of communication in cases of emergency. Without proper communication equipment, range herders and livestock production workers would be unable to seek and obtain assistance in cases of emergency. A majority of employers and employer associations agreed that electronic communication devices can help employers monitor the health and well-being of workers and the herd. Even when working in pairs, a communication device remains necessary because in the event that one worker needs emergency assistance on the range, the second worker would not likely be able to cause EMTs to arrive quickly without a communication device. Furthermore, we interpret the phrase "persons capable of responding to the worker's needs in case of an

emergency” in paragraph 655.210(d)(2) as necessarily including first responders and other emergency personnel, in addition to the employer. Thus, workers must be free to use the electronic communication device to contact directly, without first contacting the employer, first responders or others capable of responding to the worker’s needs in an emergency. We also interpret the phrase “effective means of communicating” in paragraph 655.210(d)(2) to mean that employers must have the ability to address language barriers in the event of an emergency. Employers can address language barriers by having on staff or otherwise making available, such as through a conference call, a person capable of speaking the worker’s language and communicating the worker’s needs, or by using translation technology (e.g., computer software, translation devices, etc.). However, the Department has declined to prescribe a specific type of communication device, since the conditions, terrain, and particular circumstances will influence the feasible types of communication. Finally, although employers may choose to do so, we clarify that this Final Rule does not require an employer to pay for workers’ personal calls to friends or family or to supply or pay for communication devices beyond what is necessary for emergency contact with the employer and emergency first responders.

After considering all the comments on this subject, the Department also revised and added two subparagraphs in paragraph 655.210(d)(2) to clarify the employer’s obligations. First, subparagraph 655.210(d)(2)(i) requires employers to include in the job order a simple statement specifying the type of electronic communication device(s) that the employer will provide, free of charge or deposit charge, to the worker during the entire period of employment. Second, under subparagraph 655.210(d)(2)(ii), the employer must specify in the job order the means and frequency with which the employer plans to make contact with the worker to monitor the worker’s well-being if there are periods when the worker is stationed in locations where electronic communication devices may not operate effectively. Subparagraph (ii) also clarifies that such contact must include either (1) arrangements for workers to be located in geographic areas where electronic communication devices can operate effectively on a regular basis, or (2) arrangements for regular, pre-scheduled, in-person visits between workers and the employer, which may

include visits between workers and other persons designated by the employer to resupply the workers’ camp (e.g., “camp tenders”). The Department concludes that this provision provides a suitable solution to the concern—acknowledged by many commenters—that range sheep, goat and cattle herders often work in isolated areas where electronic communication devices will not function at all times. Comments from employers also indicated that many employers are currently complying with this requirement and that this practice is effective in providing workers regular contact with the employer. One commenter suggested that employers that station workers in pairs while in areas with unreliable or no cell phone service should be required to make in-person contact with only one worker in the working pair. The Department concludes that in such instances, in-person contact with only one member of the working pair is sufficient for purposes of establishing an alternative means of communication for the second worker, but only if in making in-person contact with the first worker, the employer verifies the health and safety of the second worker. This rule adequately protects each worker employed, while responding to the employers’ need for efficiency and flexibility. Additionally, the disclosure requirements in the Final Rule will serve to inform workers on how best to seek help in the event of an emergency, and provide a suitable solution to the concern—acknowledged by all—that range herders and livestock production workers often work in isolated areas where electronic communication devices will not function at all times.

In light of the comments from numerous employers and employer associations about the need for flexibility in determining the best method for providing workers access to emergency services, the Final Rule does not mandate the use of a specific electronic communications device. The Department has also decided not to require employers to provide workers access to satellite phones as a substitute for in-person employer-initiated contacts. Comments received from employers overwhelmingly rejected this approach, citing the costs and reliability of satellite phones, as well as the need for flexibility. The Department, however, clarifies that employers should consider and keep up with advances in technology when selecting appropriate electronic communication devices. A comment from the Western Watershed Project asserted that employers must provide workers with

working or rechargeable batteries to power electronic communication devices for the amount of time spent in remote areas. In response, we clarify that the requirement to provide an effective means of electronic communication means that the device must be operable at all times. Therefore, the employer must provide the worker with an adequate power source for the device.

The Department will require the standards set out above without defining “regular” contact or imposing minimum in-person contacts, but, as mentioned above, will require the employer to disclose the frequency of contact in the job order. In the absence of evidence demonstrating pervasive issues with worker access to emergency services, a specific frequency requirement for in-person contacts is unnecessary. This choice strikes a suitable balance between the Department’s legitimate interest in protecting H–2A sheep, goat and cattle herders with the employers’ need for flexibility in determining the appropriate method for providing workers access to emergency services.¹³

iii. Tools, Supplies and Equipment

(1) Comments

Employers and their associations generally commented that employers provide all the tools, supplies and equipment needed for the job, at no cost to the workers. Some employer commenters listed examples of items that are provided for their herders. For example, F.I.M. Corporation commented that they provide free of charge “clothes, medicine, blankets, rain coats, boots, etc.” Mule Head Growers commented that their herders have ATVs and herding dogs, and that they provide all other supplies requested by the herders. Cindy Siddoway of Siddoway Sheep Company’s comment listed the following items as necessary

¹³ The Worker Advocates’ Joint Comment urged the Department to prohibit employers from opening workers’ mail, which we note is otherwise prohibited under federal law. See 18 U.S.C. 1702. They also stated that employers sometimes prohibit workers from allowing visitors (including healthcare professionals); using a radio, or possessing reading materials. We conclude that there is no reasonable basis upon which an employer should restrict a worker’s use of a radio or possession of reading material obtained at the worker’s own expense. With regard to access to visitors, this Final Rule requires the employer to permit access to emergency personnel to respond to worker illness or injury. We decline to set specific federal standards here governing access other than to emergency personnel. In accordance with the requirement to comply with all applicable Federal, State, and local laws and regulations, employers are reminded of obligations to adhere to local laws providing such access.

to perform the work safely and effectively, “[h]orses, tack equipment, rain gear, guns, shovels, ax, various tools, sheep hooks, protective clothing and eyewear, gloves, binoculars, flashlights, batteries, lanterns, wood, and fuel.” Another ranching operation buys what the herders need including clothes, boots, and tools. Paul Nelson of Nelson Bros. Farm stated that they make sure the herders have good clothes to wear, warm hats and gloves, and tools needed to maintain the fences. The Wyoming Farm Bureau Federation commented that “[w]e believe that it is important to have proper tools and equipment provided for the worker as well as the necessary supplies for the work that needs to be done. For instance, a saddle for the horse or leather to repair the saddle or dog food for the herding and guard dogs.” They requested further clarification on the type of boots referred to in the preamble to the NPRM. Larson Livestock commented their herders provide them with a list of the supplies they want, and that the employer purchases the items at no cost to the workers, “with the exception of any personal items they may order such as cigarettes, DVD players, etc.” and deliver the supplies to the workers at their sheep camps.

Employers and their associations commenting on this issue emphasized that required tools, supplies and equipment will vary among ranches due to differing climates, weather conditions, and assigned duties. Items required by the employer on one ranch may be completely unnecessary on another ranch due to the nature of the work. For example, Eph Jensen Livestock commented that “[w]ith the diversity of size, location, and management practices of sheep ranches, it would be impossible to make a checklist of items that need to be provided. This is already monitored by the WHD and penalties are imposed for violations.” The employer further commented that, in its view, the trouble is a lack of practical understanding in DOL investigations, and recommended that in enforcement actions, employers should be allowed the opportunity to explain why certain items were or were not provided.

Due to variety in the items required, several commenters opposed including a list of typically required items in the regulation or in the job order. For example, Billie Siddoway of Siddoway Sheep Company commented that “[b]ecause the provision of equipment varies among ranches and among employees on each ranch, it would be preferable to modify the proposed rule so that an exhaustive list of equipment

is not required. Rather, an employer should be able to state generally that the equipment necessary to carry out the job duties will be provided.” Ms. Siddoway further commented that “[i]f the Department deems certain equipment to be significant (e.g., horse, herd dog, guard dog, gun, mobile telephone), then the employer could identify those specific items in addition to the more general statement that necessary equipment will be provided.” Kay and David O. Neves, who own a sheep operation, commented that they “do provide items necessary for [the] job” but they “do not think all these items need to be specified in the job order. The statement that employers provide needed items should be enough.”

Mountain Plains and Western Range commented that the tools, supplies and equipment required to do the work safely and effectively depends on the time of year or location of the work. They explained that “[t]he items suggested in the NPRM are among those used on the range, binoculars, firearm, boots, rain gear, an ATV or four-wheeler, and/or a horse, but this list should not be considered exhaustive nor mandatory. During different times of the year or in different parts of the West, some or all of these items would be strictly necessary while others would be entirely useless.” Mountain Plains and Western Range further commented that including specific requirements of items to be provided “will not increase job safety or efficiency but would simply provide a ‘gotcha’ opportunity for ambitious plaintiffs lawyers.”

Additionally, some employer commenters noted that items provided should be “within reason” and that the Department’s proposal does not take into account personal preferences or other factors. Sheep ranchers John and Carolyn Espil stated that “[i]t is doubtful that the DOL investigators could, in the scope of their investigation, determine whether the charge was for an item requested by the herder for his personal possession or if it was an item that the employer should provide.” They gave the example of “boots” as a required item, stating that the Department gives no variance for price of items, personal preference or frequency of purchase. They commented that they already provide all bedding, clothing and boots within reason, but that the Department’s proposal would eliminate all expense for the worker. Eph Jensen Livestock commented that “there has been no accountability placed on the worker for neglect of tools or equipment that employers provide.”

On the other hand, the Worker Advocates’ Joint Comment suggested that the regulation “include an explicit non-exclusive list of such items that are typically required by the nature of the work under [this rule] to avoid employers circumventing this requirement with their own interpretation” of what is required by the job. As they explained, foreign herders and range workers often bring little with them to the United States because they have been assured that “everything will be provided.” The Worker Advocates’ Joint Comment stated that because the TEGs have never “described the precise items that need to be provided . . . there has never been a consistent understanding among the workers and the industry of what this promise truly encompasses,” so that upon arrival in the United States, foreign workers learn that, while the employer will purchase many of the items needed for the job, the cost of the items is often deducted from the worker’s pay. The Worker Advocates’ Joint Comment listed several items that they find are required by the nature of the work to perform the job safely and effectively and should be provided free of charge, including binoculars, a rifle/gun, a knife, a trained horse, lighting, bedding, outer wear to protect the worker from the elements, and disposable gloves and disinfectant. They further recommended that, at a minimum, the Final Rule should specify “those categories of items that the Department considers necessary for these jobs, such as ‘bedding’ and ‘outerwear to protect worker from elements.’” The Worker Advocates’ Joint Comment also supported the NPRM provision requiring employers to list the items that will be provided in the job order, as this will “help employers clarify with the Department the kind of tools that must be provided” free of charge and “the Department can then review whether an employer’s job order specifies many of the common items discussed above and require clarification or correction of any deficiencies.” They further recommended that the job order include the list they suggested of specific items and blank lines for any additional items.

(2) Discussion

As explained in the NPRM, although the H-2A regulations currently require employers to provide, free of charge, all tools, supplies and equipment necessary to complete the duties assigned, Departmental investigations have found instances where employers have failed to supply the necessary tools, supplies and equipment for the job, such as

boots, raingear or an ATV. 80 FR at 20304. The Department has also found instances where employers charged the workers for such tools, supplies or equipment, bringing the workers below the required wage. *Id.* To address these issues, the NPRM proposed that employers must provide tools, supplies and equipment required by the law, the employer, or the nature of the work to perform the job safely and effectively, and these items must be provided free of charge or deposit charge. *Id.* The NPRM also proposed to require employers to disclose in the job order those items that will be provided and inquired whether it would be helpful to include a list of typically required items in the regulations. *Id.*

Based on the comments received, the Final Rule retains the NPRM provisions as proposed, and does not include a specific list of typically required items in the regulations. The Department concludes that it is appropriate to specify in the Final Rule that employers must provide, free of charge or deposit charge, all tools, supplies and equipment required by law, the employer, or the nature of the work to perform the job safely and effectively and to list which items will be provided free of charge or deposit charge in the job order. The comments reflected that although many employers provide all necessary items and provide them free of charge or deposit charge, it is helpful to include in the Final Rule the requirement that the employer must provide all tools, supplies and equipment free of charge, because it provides clarity to workers and employers on the types of items considered required for herding and range production of livestock occupations. If items are only required at certain times of the year, the employer is only required to provide those items during those periods. However, DOL concludes that it is necessary for the employer to disclose that those items will be provided in the job order so that workers are aware of which items will be provided prior to accepting the job. If an employer wishes to further specify in the job order that certain items will be supplied only during specific periods, DOL would not object to this. Additionally, while the standard H-2A regulations require employers to provide, free of charge, all tools, supplies and equipment necessary to complete the duties assigned, the language “by law, by the employer, or by the nature of the work to perform the duties assigned in the job offer safely and effectively” provides additional guidance on the type of items that must

be provided free of charge or deposit charge. This provision does not require employers to provide items for the worker’s entertainment, such as magazines, CDs and DVDs, or other items that are not required by the job, but employers may choose to do so. As many employers noted, they already supply all items requested by their workers; the Department encourages ranchers to continue to these practices. Some charge the worker for personal items that the workers request, while others do not.

We further conclude that requiring employers to list which items will be provided free of charge or deposit charge in the job order will ensure that workers are aware of what items to expect to be provided, in advance of accepting the job. Additionally, including this list will serve to notify the Department of the types of items required in these occupations, and, as noted by the Worker Advocates’ Joint Comment, the Department may review those items and ask for clarification or correction of any deficiencies. In the event of an investigation, the Department may review those items included in the job order; however, the Department is not precluded from determining that additional items not included in the job order were required for a particular worker under the terms of the Final Rule. Additionally, we note that we currently allow, and will continue to allow, an employer in an investigation to provide its explanation of why certain items were or were not provided.

Finally, as noted, we decline to include a list of typically required items in the Final Rule. As demonstrated by the comments received, the tools, supplies and equipment required by employers or by the nature of the work will depend on a number of circumstances, such as the terrain, the season, and the climate. As discussed above, the requirement that employers list in the job order those specific items that will be provided to herders will meet the goal of providing information to workers and to the Department, while avoiding the risk that specifically mandated requirements may become outdated, unnecessary or irrelevant. We note that the term “required” in § 655.210(d)(1) means all tools required by law, by the employer, or by the nature of the work to perform the work safely and effectively. The Department further notes that the preamble discussions here and in the NPRM provide examples of items that may be required by the nature of the work, such as boots, binoculars, a gun, an ATV, or a horse. Additionally, § 655.230

addresses range housing standards, and as fully discussed in preamble Sec. IV.E., certain items are required to be provided to meet those housing standards, such as bedding and heating equipment (or protective clothing where appropriate). As with all required tools, supplies and equipment, these items must be provided to the worker free of charge or deposit charge and listed in the job order.

d. Section 655.210(e)—Meals

i. Background

Currently, as required under the sheep and goat herding TEGL, and pursuant to industry practice for the range production of cattle, H-2A employers employing workers in these range occupations must provide food, free of charge, to their workers.¹⁴ The TEGL for sheep and goat herding established requirements for meals, and the cattle herding TEGL was silent on the issue of meals, leaving the issue to be covered by the standard H-2A regulations. The NPRM generally adopted the requirements from the sheep and goat herding TEGL for all range employers; we proposed to require all these employers to specify in the job order and provide to the worker, without charge or deposit charge, either three sufficient meals per day, or convenient kitchen facilities and adequate food provisions to enable the worker to prepare his own meals.¹⁵ The terms “sufficient” and “adequate” were new introductions from the requirements in TEGL 32-10.¹⁶ The Department also sought comment on what constitutes a sufficient meal for range workers, given the physically demanding nature of their work, as well as what constitutes adequate food given the remote location of these workers. 80 FR at 20305.

The Final Rule maintains the requirement that employers must provide either three sufficient meals a day, or furnish free and convenient

¹⁴ Additional background and comments received about the proposed requirement that food be provided without charge to workers are discussed in Sec. IV.C. of the preamble related to setting the herders’ wage in § 655.211 of the Final Rule.

¹⁵ Cooking and eating facilities are discussed in Sec. IV.E.2. of the preamble, which addresses housing standards set in § 655.235 of the Final Rule.

¹⁶ Additionally, we proposed to require that employers provide workers with an adequate supply of potable water, or water that can be easily rendered potable, and the means to do so, when working on the range. The potable water requirement is discussed in Sec. IV.E. of the preamble related to § 655.235(b) of the Final Rule, which establishes the requirements that employers must follow in supplying water for range workers. We have added a cross-reference in § 655.210(e)(2), which governs meal standards, to § 655.235(b), related to water standards.

cooking facilities and adequate provision of food to enable the worker to prepare his own meals free of charge or deposit charge. The Department is also revising the proposed rule to provide additional guidance to employers on what constitutes “sufficient” and “adequate” meals and food. Under paragraph 655.210(e)(1) of this Final Rule, to be considered “sufficient” or “adequate,” the meals or food provided to range workers must include a daily source of protein, vitamins, and minerals.

ii. Comments

Comments received from worker advocates, private citizens, an industry magazine editor, a State government office, employers, and employer associations reflect general agreement that employers should provide range workers with “adequate” meals or “sufficient” provisions of food to prepare healthy, nutritious meals. For instance, in their joint comment, Mountain Plains and Western Range stated that, “[t]he physical demands of the job call for a protein-rich diet for the hearty men that perform this work. . . .” Billie Siddoway of Siddoway Sheep Company, Inc. also stated that “[d]elivering food is a necessary part of range employment because employees do not have ready access to shopping markets.” Other employers agreed that range workers “need and deserve good food” and should be “adequately fed.” One employer, in expressing his support for the proposal to require sufficient and adequate food, opined that “if the workers are happy, well-nourished and content, they will properly care for our animals and properties.”

Commenters disagreed, however, on whether employers are currently providing adequate meals or sufficient food to range workers. Several employers stated that they provide a variety of food, including meat and fresh produce, and accommodate worker preferences for specific foods and quantities. Billie Siddoway of Siddoway Sheep Company, Inc. described their practice of providing hot meals and food to workers as follows:

During the winter lambing season, we employ[] a cook who prepares three hot meals each day. When the [workers] are on the range, they prepare their own meals. On our ranch, each [range worker] provides us with a grocery list. Every eight to ten days, depending on terrain and conditions, we purchase the items on the list and deliver them to the requesting [range worker].

This comment also noted that Siddoway provides meat to range workers, such as lamb, mutton, elk, and buffalo, which are raised on the Siddoway ranch. Other

employers described having similar practices of supplying food that is selected by the range workers and delivered by the employer at intervals that vary depending on the season, terrain, and other factors. At least one other employer indicated that he employed a cook who delivered fresh, hot meals to workers three times a day.

On the other hand, the Worker Advocates’ Joint Comment reported instances when food is not delivered to range workers in a timely manner, and provides accounts of workers “being sent by employers to steal fruits and vegetables from the nearby orchards for their own consumption.” A private citizen also recounted instances where employers have forgotten to deliver food supplies to range workers and where employers have supplied food unfit to eat. One other private citizen noted that she visited with range workers who reported going over a month without receiving food from the employer.

The Department also received a number of comments about how and to what extent the Final Rule should specify the employer’s food provision obligation. The Worker Advocates’ Joint Comment emphasized that range workers need sufficient quantities of food for health maintenance, disease prevention, and preventing vitamin deficiencies. They stated that the terms “sufficient” and “adequate” used in the proposed rule do not provide clear guidance on the amount and kind of food necessary for workers engaged in physically demanding work. Thus, they requested that the Department require in the Final Rule “a daily source of protein and vitamins and minerals” and that employers provide range workers with “fresh food when possible.” They suggested meats, beans, and eggs as permissible sources of protein, and fruits, vegetables, and oils as examples of the remaining vitamins and nutrients. The Worker Advocates’ Joint Comment also requested that we set minimum daily calorie requirements, variety recommendations, and food safety standards using federal guidelines, including guidelines from the National Institutes of Health and the U.S. Department of Agriculture. Specifically, they stated employers should provide to each range worker enough food to meet a minimum daily calorie requirement of 3,000 to 4,000 calories (or 21,000 to 32,000 calories per week), and provide range workers with more food during periods when they are engaged in higher levels of activity. One private citizen also suggested that, given the difficulty with refrigeration on the range, the Department should consider requiring

employers to provide extra food in order to take spoilage into account.

Comments from employers and employer associations, on the other hand, requested that the Department adopt a flexible, case-by-case approach in defining the employer’s food provision obligations. Mountain Plains and Western Range stated that food provision requirements involving calorie counts or menus are unnecessary, arbitrary, and would create “a logistical nightmare” for the Department to enforce and for employers to comply with. They also noted that each worker has his own preference for food, and a “one size fits all” approach mandating a particular diet for range workers would violate those preferences. One employer suggested that imposing calorie requirements and food delivery is beyond the Department’s purview. A comment from the Wyoming Farm Bureau Federation suggested that the Department should simply provide clear language about what the employer is not required to provide (e.g., soda pop), rather than listing what it must provide.

iii. Discussion

Based on the comments received, the Final Rule retains the proposed standard, now found at paragraph 655.210(e)(1), requiring employers to specify in the job order and to provide to range workers, without charge or deposit charge, either three sufficient meals a day, or free and convenient cooking facilities and adequate provision of food to enable range workers to prepare their own meals. Comments from worker advocates, private citizens, employers, and employer associations revealed general agreement that, given the unique and isolated nature of range herding, employers should be required to provide range workers with adequate and sufficient meals and food.

The Final Rule also revises the proposed regulation by adding a clause at the end of paragraph 655.210(e)(1), stating that to be “sufficient” or “adequate,” meals or food provided by the employer must include a daily source of protein, vitamins, and minerals. The Final Rule reflects a basic nutritional framework and also retains employers’ flexibility to accommodate workers’ preferences, as well as delivery and storage realities. Such a requirement is appropriate given that range workers are often in isolated locations and entirely dependent upon their employers for adequate food to meet their nutritional needs. This provision also establishes a more objective standard for employers to

evaluate the type of food that they must provide to range workers.

Having established the general parameters for minimum food requirements, we conclude that further regulating food provisions by mandating a specific calorie count or specific food delivery intervals is unnecessary. In addition, a one-size-fits-all approach would create significant difficulties given that workers' preferences may vary and food delivery schedules may depend upon the location of work. Nonetheless, we clarify that employers are encouraged to consult and may rely on existing federal guidelines for minimum calorie counts, variety requirements, and/or food safety standards when making decisions about food provision, taking into account the physical conditions and requirements of this work. We further clarify, consistent with the proposal from the Worker Advocates' Joint comment, that acceptable sources of protein include, but are not limited to, meats, beans, and eggs, and acceptable sources of vitamins and minerals include, but are not limited to, fruits, vegetables, and oils. Furthermore, in meeting the food provision requirements under this Final Rule, employers should strive to provide range workers with fresh food when possible.

e. Section 655.210(f)—Hours and Earnings Statements

i. Background

The TEGs for employers engaged in sheep, goat and cattle herding require job orders to comply with the standard H-2A requirements, "unless otherwise specified" in the TEGs. TEG 32-10, 4; Attachment A, I(B), (C); TEG 15-06, Change 1, 4; Attachment A, I(B), (C). Both TEGs provide, with regard to earnings records and statements, that an employer must keep accurate and adequate records with respect to workers' earnings and furnish workers a statement of earnings on or before each pay day (a requirement consistent with the standard H-2A requirement, *see* 20 CFR 655.122(k)). The TEGs further provide that, because "unique circumstances" (*i.e.*, on call 24/7 in remote locations) prevent the monitoring and recording of hours actually worked each day as well as the time the worker begins and ends each workday, the employer is exempt from reporting on these two specific requirements at 20 CFR 655.122(j) and (k). However, all other regulatory requirements related to earnings records and statements apply." TEG 32-10, Attachment A, Section I(C)(7); TEG

15-06, Change 1, Attachment A, Section I(C)(5).

The NPRM proposed to limit the special exemption from the standard recordkeeping requirements to the days "when the worker is performing duties on the open range." 80 FR at 20340. The NPRM also proposed to require employers to keep daily records indicating whether the employee worked on the open range or on the ranch or farm, and to require employers to "keep and maintain records of hours worked and duties performed over the course of the day when the worker is performing work on the ranch or farm." 80 FR at 20340. Finally, the NPRM proposed to require employers who chose to prorate a worker's wage, based upon the worker's voluntary absence for personal reasons, to keep a record of the reason for the worker's absence. *Id.*

The NPRM stated that, because the proposal requires a monthly wage, keeping and maintaining records of hours worked was not necessary for days spent on the range. 80 FR at 20305. The daily record of where the work was performed would be sufficient for the Department to assess compliance with the requirement that at least 50 percent of the worker's days be spent on the range. The preamble clarified that, where an employee spends some portion of the day on the range and some portion on the ranch, the day would count as a range day or a ranch day depending upon where the employee spent a majority of the hours worked during the workday. 80 FR at 20306. The NPRM explained that the proposed requirement to keep a record of the hours the employees worked and the duties performed for days spent on the ranch or farm would allow the employer and the Department to determine whether work that did not fall squarely within the definition of the production of livestock satisfied the proposed requirement that it be minor, sporadic, and incidental (*i.e.*, occurring during no more than 20 percent of the workdays spent at the ranch). The proposed requirement to record the duties performed at the ranch similarly was intended to allow "the Department to distinguish herder- or livestock production-related ranch work from unrelated ranch work to determine whether the work performed at the ranch is in compliance with the job order and the applicable wage rate." *Id.*

As discussed in Sec. IV.A.3. of the preamble related to § 655.201, the Final Rule eliminates the 20 percent cap on the performance of minor, sporadic, and incidental duties while workers are on the ranch or farm; therefore it also eliminates the requirement to maintain

records of hours worked and duties performed while on the ranch or farm. The Final Rule retains the NPRM's other requirements to record whether each day is spent on the range or the ranch and, if the employer chooses to prorate the required wage, to record the reason for the worker's absence.

ii. Comments

Many employer commenters objected to the recordkeeping requirements associated with the proposed 20 percent cap on directly and closely related duties while at the ranch. In some cases their concerns were based upon a misunderstanding of those requirements. For example, some commenters thought the proposed rule required them to keep track of the number of hours that workers performed each individual duty while at the ranch, or at least to track the time spent on directly related work versus actual livestock production work, rather than simply to record the total hours worked each ranch day and a description of the duties performed during the day. Thus, one herding employer, Martinez Livestock, stated that requiring the employer to individually itemize each of the incidental chores and the time spent would be time consuming. The Colorado Wool Growers Association commented that the performance of additional related chores should not "require the ranch to keep an onerous set of records, parsing out every single activity." Another rancher stated that "[k]eeping track of time an employee works in a particular situation or site makes no sense!" Other commenters specifically opposed any additional requirement to keep records of work performed on the range, stating that the added burden would be unnecessary and impractical.

Other commenters addressed the proposed recordkeeping requirements. For example, the American Farm Bureau stated that keeping "hourly records for work performed at the ranch and daily records of the work performed on the range" was burdensome and the Department "has presented no evidence that farmers have been using herding workers on the ranch more than the allowed 20 percent time." The Utah Farm Bureau Federation and the Michigan Farm Bureau agreed and further concurred with the statement that the proposal would be particularly burdensome for small ranchers; they stated that such family businesses do not have a human resources department for support, and they may not be familiar with the FLSA recordkeeping requirements because one H-2A worker may be their only employee. Another

ranch owner stated that trying to regulate hours and document what workers do every day is not practical, because animals can become sick and then “the next 2 days is spent setting up corrals, treating animals along with all the normal daily chores . . . 20 different unexpected events can happen in one day!” Another owner stated that the requirement to quantify hours spent on actual livestock tending, and the need for extensive record-keeping, is not practical or productive.

Many other commenters agreed. For example, John Espil Sheep Company stated that keeping track of their workers’ time hourly or daily would be extremely difficult or impossible, both on the range and at the ranch, because every day is different. Another sheep rancher commented that the workers irrigate pastures, harvest livestock feeds, maintain fences, clean corrals, doctor sheep and feed them, and it would be “absurd” to require recordkeeping for this work.

In contrast, Billie Siddoway, on behalf of the Siddoway Sheep Company, stated that it “would not be unreasonable to track the days each employee works on the range or the ranch,” but that it would be onerous to track hours of work and duties performed every day when workers are on the ranch. This commenter suggested that if an employee undertakes minor, sporadic or incidental work outside the definition of herding, “the employer could track those hours and job duties only” in order to allow the Department to evaluate compliance with the 20 percent rule. This commenter further stated that it “would not be unreasonable to track the hours and duties associated with” such incidental tasks as erecting temporary pens and corrals in anticipation of the lambing season, and that limiting the reporting requirement to only incidental work would likely lead to more accurate reporting.

In contrast to the comments by employers or their representatives, the Worker Advocates’ Joint Comment suggested that the normal recordkeeping requirements should be extended to these workers, regardless of where the work is performed, so that start and stop times (including for responses to emergencies), total daily hours, and duties would be recorded even for work on the range. They stated that this would allow a more accurate assessment of the appropriate number of hours per workweek to use for the monthly wage computation, and it would allow for enforcement of the hourly AEWR if workers perform duties that fall outside the scope of these regulations, such as if workers are required to repair

irrigation ditches or harvest hay. They stated that relieving employers of the standard requirements to maintain “records reflecting daily hours and job duties for open range work incentivizes misclassification.” They also asserted that “[w]ithout recordkeeping requirements, the Department cannot monitor compliance with those requirements,” and that workers “face the daunting task of having to reconstruct covered and uncovered work hours and of having to convince a judge or jury that they are telling the truth” when they seek to recover back wages at the higher hourly AEWR rate. In the alternative, they sought clarification that the exemption from normal recordkeeping applies only when the worker spends an entire day on the range and not when both range and ranch duties are performed during a single day. The Worker Advocates’ Joint Comment also noted that any burden from the extra recordkeeping would fall on the employees, not the employers, but that it could involve a simple daily timesheet or calendar that the employer collected each month. Finally, they stated that employers already have timekeeping systems for their other employees, and that the new requirements would add little cost but would provide records important for monitoring and enforcement. The Western Watershed Project concurred that records of actual hours worked should be required.

iii. Discussion

The Final Rule retains the proposed requirement to track days at the ranch versus days on the range because that is essential to allowing the employer, and the Department if necessary, to assess compliance with the requirement that a majority (more than 50 percent) of the workers’ days be spent on the range in order for these rules to apply. Moreover, that requirement imposes only a minimal recordkeeping burden. We understand from the comments that employees generally will work on the range for several months at a time, and then they may be on the ranch for two months, such as for lambing, before again leaving for months on the range. Because the employer simply needs to record (by, for example, checking a box) where the employee worked each day, and because that response will be the same for months at a time, the burden is inconsequential. Moreover, the employer commenters did not object to this aspect of the proposal.

The Final Rule also retains the NPRM’s requirement to record the reason for a worker’s absence, if the employer chooses to prorate the

required wage. The required wage may be prorated only if an employee voluntarily is unavailable for work for personal reasons, such as to return home due to a family member’s illness. The notation of the reason for the worker’s absence will allow the Department to verify whether any deduction that the employer chooses to make from the worker’s required wage was made for appropriate reasons. The need to make such an entry is likely to arise only very rarely and for very few workers; therefore, the burden is minimal. Moreover, employer commenters did not object to this requirement. Accordingly, the Department retains the requirement so that it will have available for later review a contemporaneous explanation for any deductions from the required wage.

The Final Rule eliminates the proposed requirement to maintain records of hours worked and duties performed while on the ranch or farm, because the Final Rule eliminates the proposed 20 percent cap on the performance of minor, sporadic, and incidental duties while workers are on the ranch or farm. The proposed requirement to track duties performed at the ranch was intended to allow the Department to monitor compliance with the 20 percent cap, by preserving a record of the tasks performed each day, so it could be determined whether the tasks were solely those that fell squarely within the definition of the production of livestock or also included some tasks that simply were closely and directly related to herding or the production of livestock. The proposed requirement to track the hours worked while at the ranch was intended to provide the basis for a remedy for a violation when workers exceeded the 20 percent cap. In light of the decision to remove the proposed 20 percent cap from the Final Rule, the associated recordkeeping requirement is no longer necessary for these purposes.

The Department recognizes that records regarding the duties performed and the hours worked would be relevant if the rancher violates the rules by assigning duties to the workers that fall outside the scope of the herding and range livestock regulations during periods when they are not working on the range. Thus if an employer assigned a worker general ranch hand work rather than work that falls within the definition of the production of livestock (which includes all duties that are closely and directly related to the herding or production of livestock), records of the hours worked would be relevant to determining the appropriate

remedy for such a violation. That benefit has to be weighed against the burden imposed on all employers by mandating such daily record-keeping regarding both total hours and the length of time various duties were performed. Imposing that burden does not seem necessary because, if such a violation occurs, the Department's enforcement experience demonstrates that it can obtain the information necessary to prove such violations, including the information necessary to reconstruct hours to compute back wages, via worker and employer interviews during an investigation. For example, a broad variety of routine business records could provide an indication whether the worker and the herd were at the ranch or the range during various periods (depending upon the particular rancher's production methods), such as contracts with wool shearers, contracts with truck drivers or those purchasing lambs, veterinarian bills, water bills, gasoline bills, electric bills, and cell phone records. The Department's experienced investigators use all relevant records, as well as the results of their interviews, when evaluating the facts of cases in which time records do not exist or are inaccurate.

f. Section 655.210(g) and (h)—Rates of Pay and Frequency of Pay

i. Background

The wage rate required by the standards in § 655.210(g) of this Final Rule is also discussed in Sec. IV.C. of the preamble related to the wage methodology standards in § 655.211, which also governs the applicable wage rate. In addition to the many comments received on the wage methodology, we received a handful of comments on paragraphs 655.210(g) and (h) related to commissions, bonuses, and other incentives, and pay frequency and access.

The TEGLs do not address the issue of whether an employer may pay a wage rate based on commissions, bonuses, or other incentives. Under the standard H-2A rules, at 20 CFR 655.122(l)(1), employers are barred from offering or paying a wage rate based on commissions, bonuses, or other incentives unless the employer guarantees and pays at least the required wage for each pay period. Section 655.210(g)(1) of the proposed rule departed from the standard H-2A requirement, and barred pay rates based on commissions, bonuses, or other incentives entirely. The proposed rule further clarified that all payments must be made free and clear without any

authorized deductions. Recognizing that herders are often paid through direct deposit or wire transfer given the remote nature of the work, the preamble further provided that if the employee:

voluntarily requests that the employer deposit the wages into a bank account or send a wire transfer back to the worker's home country, for example, the employer is still responsible for ensuring that wages are paid when due. The employer may not derive any benefit or profit from the transaction and must be able to demonstrate that the wage payment was properly transmitted to and deposited in the designated bank account or recipient on behalf of the employee.

80 FR at 20306. On the issue of pay frequency, § 655.210(g) and (h) of the NPRM continued a long-standing practice based on the TEGLs and required workers to be paid not less frequently than monthly. We specifically invited comment on the issue of how frequently workers should be paid. *Id.*

ii. Comments

A few employers commented on the prohibition of wage rates based on commissions, bonuses, or other incentives in the NPRM. The joint comment from Vermillion and Midland opposed this requirement. This comment pointed out that a flat prohibition was inconsistent with the rule in the rest of the H-2A program and stated that such payments should be permitted, provided that the employer guaranteed the required wage. Siddoway Sheep recommended that DOL permit employers to withhold a portion of wages as an incentive for the employee to complete the contract period and to discourage workers from leaving to work in other industries. A third employer, Lava Lake Land & Livestock, stated that it was "the American way" to pay for performance and stated that such payments should be permitted if disclosed in the job order and advertised. This employer stated that the required wage should be assessed on an annual basis so that any bonuses could be counted toward compliance with the wage requirement.

We received only a few comments on the issue of pay frequency. Both Edward Tuddenham, an attorney who represents workers, and the Worker Advocates' Joint Comment stated that DOL should require workers to be paid at least twice monthly, consistent with the requirements in the rest of the H-2A program. *See* 20 CFR 655.122(m). They expressed the view that payment no less than twice monthly was preferred by workers. One individual employer stated that its herders had never requested to be paid more frequently

than monthly but had sometimes asked for advances on wages. This employer asserted that it did not object to paying its workers more frequently than monthly if they would prefer that.

Both the Worker Advocates' Joint Comment and the Tuddenham comment further requested that DOL take additional steps to provide workers with "real access to their wages." These commenters expressed concerns that workers are not provided with the means or time off to go to the bank or check cashing facility and thus are overly dependent on their employers in accessing wages. The Worker Advocates' Joint Comment noted that workers typically either receive wages by direct deposit or have wages sent directly to their families in their home countries. This comment recommended that DOL require by regulation that employers offer the worker the option to receive wages by check, cash, or direct deposit, and asked that DOL require employers to provide workers with physical access to banking facilities. Both comments asked DOL to impose additional regulatory standards, such as requiring by regulation that, if direct deposit is used, all banking information be provided to the worker, and that the worker be provided with the necessary bank cards or other items needed to withdraw these funds.

iii. Discussion

On the issue of bonuses, commissions, and incentives, we agree that the standard H-2A rule should apply. *See* § 655.122(l)(1). Accordingly, under this Final Rule, employers may make payments based on bonuses, commissions, and incentives provided that the full rate required by § 655.211 of this Final Rule is guaranteed and paid when due. In addition, we agree that the full offered wage rate, including any commissions, bonuses, or incentives, must be included in the job order and advertised to U.S. workers, because U.S. workers must be apprised of the full wage offered through the job opportunity.

We decline to adopt the other recommendations suggested by commenters regarding commissions, bonuses, and incentives. As explained in the preamble to the NPRM, the requirement to pay the required wage necessarily means that payments must be made when due to the worker (in this case, twice monthly, as discussed below). 80 FR at 20306. Authorizing employers to withhold a portion of the workers' pay after work has been performed would be wholly inconsistent with this requirement and with the standard H-2A regulation. The

recommendation that DOL only examine whether the required wage rate has been met at the end of the year would have the similar effect of permitting employers to withhold wages due for work performed and is, therefore, rejected.

We agree with the comments recommending that we use the standard H-2A pay frequency, and the Final Rule requires that payments be made at least twice monthly. See § 655.122(m). No employers objected to more frequent intervals beyond a single monthly payment, and calculating the twice-monthly payment can be easily accomplished by evenly dividing the required monthly rate into two payments.

On the issue of access to wages, we note that generally payment must be in the form of cash or instrument negotiable at par (*i.e.*, cash or cash equivalent). See 29 CFR 531.27. WHD has interpreted this requirement to provide that payment may only be made through direct deposit with the worker's consent and only if the workers have the alternate option of receiving payment through cash or check. See WHD Field Operation Handbook 30c00(b) (June 30, 2000). The same requirement would apply to the voluntary assignment of wages through wire transfers to a designee of the worker. See WHD Field Assistance Bulletin 12-3 (May 17, 2012). Neither these general rules nor the regulatory requirements of the general H-2A and H-2B programs require that the employer provide workers with options for how to receive their pay, provided that the worker receives payment either in cash or through an instrument negotiable at par.

We decline to accept the invitation to develop special rules for the types of payments required to be made to workers in these occupations or to set intervals at which workers must be provided physical access to banking facilities, which would go beyond DOL's obligation to set standards that will protect against adverse effect to U.S. workers. However, given the remoteness of the physical location of work covered by this rule, we encourage employers to continue what appears to be the widespread practice of providing the option for workers to receive payments through wire transfers to a designee or through direct deposit. We further clarify that, because direct deposit may only be used where the worker elects it, an arrangement under which the worker's pay is deposited into a bank account but the worker does not have the information needed to access the bank account, such as the account number, suggests that the

worker has not consented to receive payment through direct deposit. Therefore such an arrangement is not permitted.

C. Section 655.211 Herding and Range Livestock Wage Rate

1. Background: The TEGLs and the NPRM Proposals

Under the standard H-2A program, an employer must pay the higher of the hourly Adverse Effect Wage Rate (AEWR), which is based on the combined wage rate for field and livestock workers reported in the Farm Labor Survey (FLS) conducted by the U.S. Department of Agriculture (USDA); the prevailing wage rate or piece rate; the State or federal minimum wage; or an agreed-upon collective bargaining wage rate.¹⁷ 20 CFR 655.120(a).

Under the TEGLs, the AEWR for herder occupations is set at the prevailing wage rate of U.S. workers based on surveys conducted by the State Workforce Agencies (SWAs). For these herding occupations, the wage rate from the prevailing wage survey has most often been a monthly wage rate.

The NPRM proposed significant changes to the wage methodology governing H-2A workers engaged in sheep, goat, and cattle herding. As discussed in the NPRM, the dearth of information on the wages of U.S. workers in these occupations has made setting the AEWR based on the SWA surveys unsustainable. 80 FR at 20306-20308. Few employers provide U.S. worker wage information in response to prevailing wage survey requests for these occupations, making it difficult for SWAs to submit statistically valid prevailing wage findings to OFLC. Under the TEGLs, the SWAs use *ETA Handbook 385* to collect prevailing wage results. Employers are not required to report data in response to the survey data request. Often, and almost always more recently, the SWAs determine that there are no survey results or the survey does not yield statistically valid results. Thus, for many years, the Department has been unable to determine a statistically valid prevailing wage rate in each State in which one is needed, requiring the OFLC Administrator to use the survey

¹⁷ The AEWR is established in order to neutralize any adverse effect on U.S. workers resulting from the influx of temporary foreign workers. Employment and Training Administration, Labor Certification Process for the Temporary Employment of Aliens in Agriculture and Logging in the United States, 52 FR 20496, 20502 (June 1, 1987); see also 75 FR 6884, 6891-6895 (Feb. 12, 2010). The AEWR provides that the wages of similarly employed U.S. workers will not be adversely affected by bringing in foreign workers.

results from another area or State to set the wage, or, under earlier guidance, to set the wage based on a previous year's wage rate. See Field Memorandum 24-01, TEGL 32-10, TEGL 15-06, and TEGL 15-06, Change 1.

Because almost every State experienced years in which no wage report could be statistically verified, wage stagnation across these occupations has been the inevitable result in all but two States.¹⁸ Under the current procedures, wage rates are currently set at \$750 per month for sheep and goat herders in most States and \$875 per month for cattle in all States.¹⁹ The current minimum salary for sheep herders in California is \$1,600.34 per month, and, effective January 1, 2016, the minimum monthly salary for sheep herders will be \$1,777.98. Under Oregon's minimum wage law, the required rate is \$1,603.33 per month for range workers (calculated based on the State minimum wage multiplied by 2,080 hours and divided by 12 months) and is adjusted annually based on increases to the State minimum wage that are based on the CPI-U. Or. Rev. Stat. 653.025(2).

Unlike the requirements in the standard H-2A program, sheep and goat herding employers are required to provide food to the workers free of charge under TEGL 32-10. Although the current cattle production TEGL 15-06, Change 1, does not prohibit employers from deducting the cost of food in accordance with the standard H-2A program regulations, since 2013 employers have been required to provide food free of charge based on the wage surveys from the SWA. Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States: Prevailing Wage Rates for Certain Occupations Processed Under H-2A Special Procedures; Correction and Rescission, 78 FR 19019, 19020 (Mar. 28, 2013).

Section 655.211(a) of the NPRM proposed to require employers to

¹⁸ California and Oregon each have established wage rates applicable to these occupations. See Cal. Labor Code 2695.2(a) (West 2003); Or. Rev. Stat. 653.020(1)(e), 653.010(9); see also Technical Assistance for Employers in Agriculture, available at http://www.oregon.gov/boli/TA/pages/t_faq_tagric.aspx. Oregon's sheep and goat herder wage rate for the H-2A program was, until recently, set by a legal settlement in *Zapata v. Western Range Association*, Civ. N. 92-10-25, 244L (Ore. 1994). However, Oregon's current interpretation of its minimum wage law, which is applicable to these occupations, requires a payment higher than that required by the *Zapata* settlement. See http://www.oregon.gov/boli/TA/pages/t_faq_tagric.aspx.

¹⁹ Although the most recent determination for cattle herders in Oregon was \$875/month, the current wage rate required by the application of the State minimum wage law in Oregon, see footnote directly above, requires a significantly higher wage.

advertise, offer, and pay a wage that is the highest of the monthly AEWR, an agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action. We proposed to continue to use a monthly AEWR for these occupations because of the difficulties in tracking and paying an hourly wage rate to workers engaged in the herding or production of livestock on the range due to the remote location of the work and the sporadic and unpredictable nature of the duty hours on any given day.²⁰ If the AEWR was increased during the work period, and the new rate is higher than the other wage sources considered, paragraph (a) of this provision proposed that employers adjust the wage rate they pay based on the new wage effective on the date of its publication in the **Federal Register**, consistent with the approach in the standard H-2A program, and with current requirements for these occupations. See 20 CFR 655.122(l) (requiring the applicable AEWR or other wage rate to be paid based on the AEWR or rate in effect “at the time work is performed”); TEGL 32-10, App. A at p. 1.

Paragraphs (b) and (c) of § 655.211 set the proposed methodology for establishing the monthly AEWR for these occupations. Due to the challenges in obtaining valid SWA wage results and the resulting wage stagnation from the existing methodology, we proposed to use a different wage source to set the monthly AEWR—the combined hourly wage rate for field and livestock workers from the FLS (“FLS-based AEWR”) used for all other H-2A occupations. In order to derive a monthly wage from this hourly rate, we proposed to use an estimate of 44 hours worked per week, which was a compromise between the pre-NPRM submissions of an attorney representing worker interests, Edward Tuddenham, and the three primary employer associations, Mountain Plains, Western Range, and ASI.²¹ The 40-hour proposal from the employer associations was based on the *Zapata* settlement, in which employer associations agreed to pay sheep herders in Oregon on a monthly salary basis, adjusted annually. The 48-hour estimate from Mr. Tuddenham was based on a review of information provided by employers on Form ETA-9142A about the number of hours employers expected herders to

work per week. Consistent with the approach in the sheep and goat herding TEGL and the current SWA prevailing wage determinations for cattle, the NPRM proposed that employers be required to provide food free of charge.

The NPRM further proposed a four-year transition of the new wage rates, with full implementation at the beginning of year five (the NPRM referred to this as a five-year phase-in). In many States in which the current monthly wage rate for sheep and goat herders is \$750, the NPRM methodology would result in a required wage rate that triples (or more) the current rate at the end of the transition period. See 80 FR at 20318, Exhibit 6.

For the reasons discussed below, and as we proposed in the NPRM, this Final Rule requires covered employers to pay a wage that is the highest of the monthly AEWR, an agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action. However, based on a review of all the comments on the rulemaking record, and for the reasons set out below, we have concluded that it is more appropriate and consistent with the Department’s obligations under the INA to use the current federal minimum wage of \$7.25/hour, rather than the FLS-based AEWR, as the basis upon which to set the monthly AEWR for these occupations. In addition, for the reasons discussed below, we have made an upward adjustment of the estimate of hours that herders work in a week, based on a review of data collected from Form ETA-9142A. Accordingly, we will calculate the monthly wage rate as: \$7.25/hour multiplied by the revised 48-hour estimate of hours worked per week. Under the Final Rule, the wage rate for these occupations will be adjusted annually based on inflation, and implementation will be transitioned over two years, with full implementation at the beginning of year three. Finally, the Final Rule requires employers to provide three adequate meals without charge to the range workers.

2. The Wage Methodology: Review of Comments and Discussion

a. Comments and Discussion of Section 655.211(a)

DOL received only a handful of comments on proposed paragraph 655.211(a) of the wage methodology. We received no comments on the requirement that an employer pay the collective bargaining agreement wage only if it is the highest applicable wage, which is consistent with the standard

requirement governing the H-2A program, and no commenters objected to the requirement that the employer pay a higher applicable State or Federal minimum wage. In addition, Western Range and Mountain Plains incorporated the requirement to pay a higher applicable State wage into their joint wage proposal, which was supported by the ASI and many individual employers, which is discussed in greater detail below. Therefore, we retain these requirements as proposed in § 655.211(a) with only three clarifying edits. First, the proposed rule stated that the State or Federal minimum wage applied only if the wage was “specific to the occupation(s).” Because that text might be read overly narrowly to exclude workers from a State or Federally required wage if the wage was generally applicable to workers (including herders engaged in the range production of sheep, goats, or cattle), this Final Rule deletes that text from § 655.211(a).²² Second, for clarity, we have removed from § 655.211(a)(2) the requirement to pay the adjusted monthly AEWR if it is “higher than the highest of the monthly AEWR.” Because adjustments will now be based on the Employment Cost Index for wages and salaries, as discussed below, this provision is no longer necessary. Third, we deleted the statement that the AEWR would be adjusted “under the FLS” because that survey will not be the basis of the wage, as proposed. This paragraph requires the application of State or Federal minimum wage law, if applicable, but as discussed below, employers employing workers in these occupations are currently exempt from application of the Fair Labor Standards Act (FLSA) Federal minimum wage.

Vermillion and Midland objected to the inclusion of the requirement that a higher wage required by judicial action be paid because that requirement is not included in the standard H-2A regulations, or in the H-2B regulations. In their view, this requirement is unnecessary, would encourage litigation, and creates the possibility of unpredictable wage obligations. This requirement that a higher wage required by judicial action be paid is consistent with ETA’s years-long application of the legal settlement from the *Zapata* case as the required wage for sheep and goat herders in Oregon. Based on our experience with the Oregon settlement, we disagree that this requirement will incentivize litigation. In addition, we

²⁰ Employers are similarly exempt from the hourly minimum wage and record-keeping requirements of the Fair Labor Standards Act for these workers. 29 U.S.C. 213(a)(6)(E).

²¹ These pre-NPRM submissions were included on the rulemaking record and were available for public inspection and comment.

²² We have made the corresponding deletion of the phrase, “specific to the occupation[,]” in § 655.210(g) as well.

note that even if the application of a settlement in a legal case related to the applicable wage was not required by our regulation, an employer would nevertheless be required to pay a higher wage if required by a court order. Accordingly, we retain this requirement as proposed.

We received a comment from one employer objecting to the requirement that the new AEWR rate be paid upon announcement in the **Federal Register**. Apparently not recognizing that this is a current program requirement, this employer questioned how employers would make immediate adjustments to the new wage rates when their contracts required a specified wage rate over a certain period. As discussed below, the required wage will be adjusted annually based on inflation, and following the transition period, we do not expect there will be significant adjustments in wage rates required from year to year as might have occurred under the TEGs. As a result, we conclude that it will not be unduly difficult for employers to adjust to the annual changes. Because this requirement is our current practice, and presently applies both to range herding employers and employers governed by the standard H-2A regulations, we have decided to retain this existing requirement. Accordingly, we maintain this requirement as proposed.

b. Use of the Farm Labor Survey-Based AEWR To Set the Monthly Wage Rate

i. Comments Opposing Use of the FLS-Based AEWR

Generally, we received hundreds of comments opposing the use of the FLS as the basis of the wage proposal from individual herding employers; employer associations including Mountain Plains, Western Range, and ASI; State and local government officials, including Governor Mead of Wyoming and Representative Jaggi of the Wyoming House of Representatives; others from Western States with a business interest in the sheep industry, such as accountants for sheep herding employers and wool processors; and SBA Advocacy. These comments primarily provided objections based on the size of the proposed increase, which, as noted previously, *see* 80 FR at 20318, Exhibit 6, would triple the current wage rate in many States. These comments stated that the proposed wage rate would jeopardize the entire herding industry. They asserted that the wage increase would cause many employers to either go out of business entirely or to downsize and greatly reduce the number of workers employed. Many

commenters stated that wages lower than those proposed, and those required under the standard H-2A rules, were appropriate to reflect other costs paid by the employer, including food, housing, work supplies and protective clothing, and transportation. Commenters expressed the view that current wages were sufficient because H-2A workers continue to accept work at current rates. Some commenters stated that low wages for these occupations were justified, given that workers were not required to engage in productive labor at all times while on the range, and had time for relaxation and personal pursuits. The vast majority of comments were from commenters affiliated with the production of sheep; few comments were received specific to cattle herding, a much smaller part of the program compared to sheep and goat herding.

The Colorado Wool Growers Association and others asserted that the wage proposal was “not grounded in the market realities” of the industry. Many employers stated that the wages proposed were too high, given that the result would be payment of higher wages for herders than for other workers in the U.S. economy, including ranch managers, or that the wages paid substantially exceed what H-2A workers would earn for the same work in their home countries. Some commented that because food and housing are paid by the employer, foreign workers are able to send their paychecks in full back to their home countries.

SBA Office of Advocacy reported that, based on its discussions with small livestock and sheep herding operations in California, Colorado, Oregon, Montana, Utah, and Wyoming, every business contacted predicted that it would reduce its operations or close operations within a few years. SBA Office of Advocacy cited a Mountain Plains Survey, in which nearly every one of the association’s 214 member respondents commented that it would downsize or shut down operations because of the high wage rates proposed. Individual employers and associations provided similar reports. The following comment from one sheep herding employer, F.I.M. Corporation, is illustrative:

For the period 2006 to 2013 our gross income from sales of wool, lambs, sheep, and hay averaged about \$1,100,000 per year. After our operating expenses our net income averaged about 2.5% to 3% of gross or approximately \$35,000 per year. This proposed tripling of sheepherder wages will require approximately \$250,000 per year in additional wage payments . . . That much money is simply not available so the Dept of

Labor will force FIM Corp and most other sheep producers that employ sheepherders to send the sheepherders home and sell the sheep.

Some individual employers also submitted their profit-and-loss statements in support of their comments that the wage increases in the proposal could not be absorbed.

The Texas Sheep and Goat Raisers Association provided estimates based upon the Idaho enterprise sheep budget²³ showing that hired labor comprises 24 percent of total operating costs for these employers, and that a three-fold wage increase would result in an 80 percent reduction in profitability (from \$83,000 in profit to less than \$17,000). Similarly, Mountain Plains and Western Range submitted an analysis based on the Wyoming enterprise sheep budget and an analysis of lamb and wool market trends for the past 20 years, which, in their view, demonstrated that using the wage rate proposed would allow the average sheepherding employer to break even only 30 percent of the time, concluding “[t]hat is an extinction scenario for employers . . .” The American Farm Bureau used data from the Utah enterprise budget in its analysis, which similarly purported to show that the proposed wage increase would result in a loss of \$16,444. The Texas Sheep and Goat Raisers Association and others commented that impacts from the wage proposed would not be felt only by ranchers but also through “multiplier” effects in related industries, including by lamb processors, wool warehouses, textile mills, trucking and feed companies, veterinarians, and fencing businesses.

Multiple commenters, including Mountain Plains and Western Range, stated that because American wool and lamb represent a small fraction of the world market (less than one percent of wool and meat production worldwide, according to an analysis from Dr. Stephen Bronars submitted with the Mountain Plains and Western Range comment), producers are unable to pass increased labor costs on to consumers. In addition, the Bronars analysis similarly provided that range cattle account for only eight percent of world beef production.

Vermillion and Midland provided an economic analysis of the impact of the

²³ An enterprise budget is a listing of all estimated income and expenses associated with a specific enterprise (*i.e.*, single crop or livestock commodity), which will provide an estimate of its profitability and break-even values. Enterprise budgets are developed and published on an irregular basis by university-based agriculture extension services with inputs from ranchers on price, yield, and costs.

wage increases under the proposal performed by a national resource law and economic policy analyst at the Lineberry Policy Center for Natural Resource Management. Largely relying on data from the NPRM, this analysis contained little new data, but rather determined that the total overall wage costs under the proposal would be greater for employers with a larger number of workers than those employing the three workers estimated in the proposal. The analysis asserted that “[w]ith fluctuating prices for livestock products, and ever increasing input costs, the cattle and sheep industries struggle to break even, much less expect a profit.” The analysis further concluded that the wage increases would raise production costs to “untenable levels” and stated that even in the highest price years “the price volatility of the livestock product market could make it difficult to absorb the added wage increase.” The analysis cited an earlier report for the proposition that livestock operations are marginal, with net ranch income per acre of \$.55.²⁴

In addition, in opposing the wage increase, the American Farm Bureau Federation (American Farm Bureau) submitted an analysis of the effect of the proposed wage rates based on historic price data from 2000–2014. That comment stated that prices for wool and lamb over the past five years (\$1.70/lb for lamb and \$1.45/lb for wool) are significantly higher (63 percent for lamb and 113 percent for wool) than averages over the 10 preceding years (\$1.04/lb for lamb and \$.68/lb for wool). Although the comment acknowledged that a wage increase of the size set out in the proposal was “manageable” at current prices, it provided alternate scenarios to evaluate the ability to absorb the wage increase given average prices for the 2000–2014 period, as well as the lowest prices for the 15-year period (\$.80/lb for lamb and \$.53/lb for wool). At the 15-year average prices, the comment projected significantly reduced profits in all States if the FLS-based AEW was paid as compared to the profits that would be achieved with current wage rates; at the lowest prices for this period, the comment forecasted a loss in all States if the full rate proposed in the NPRM was paid compared to a slim profit with current wage rates. Further, the Utah Governor’s Office submitted a comment asserting that because prices per lamb have increased from \$67.94 in

1994 to \$157.15 in 2014 (an inflation-adjusted increase of \$48.61 according to the comment) based on analysis from the Iowa State University Extension and Outreach Program, the wage increase proposed could not be absorbed by employers.²⁵

Commenters opposing the use of the FLS-based AEW used varying economic data and budget sources in attempting to demonstrate that the wage increase would force ranches to close and the industry to contract significantly. Overall, DOL received comments reflecting significant variation in estimates of wage costs through the American Farm Bureau, the Wyoming and Idaho budgets provided by commenters, and the estimates of individual commenters. Some provided analysis of wage costs compared with overall revenue to show the impact. Others used “labor costs,” for purposes of comparison, which may include other expenses such as housing or food, making any analysis of the impact of the wage increase necessarily imprecise. Further, while it also opposed the wage increase, the American Farm Bureau comment provided less dire predictions than other commenters or the Wyoming and Idaho analyses.

In addition to economic objections, many of these employers and associations further objected to the wage increase based on their view that the limited number of U.S. workers in these occupations foreclosed the need to provide for any adverse effect. According to Western Range, in 2012 twenty-two U.S. workers applied for 1,000 openings. Western Range stated that only two U.S. workers were “qualified” and were hired, and neither completed the job contract. Mountain Plains stated that in more than 1,000 openings in 2014, only two qualified U.S. workers applied. According to Mountain Plains, one U.S. worker was not interested in the job and the other was hired but quit before completing his contract.

Further, Mountain Plains and Western Range commented that, based on their experiences, higher wages in California have not resulted in increased numbers of U.S. workers applying for jobs in these occupations. According to these associations, since 2011, Mountain Plains has received 18 applications for approximately 400 sheepherder or goat/sheepherder positions in California. No similar data was provided for Western Range. The comment stated that of those

18 prospective workers, 10 were not qualified for the work and the remaining eight withdrew their applications because they were not interested in the job. According to these commenters, in their experience, there are actually fewer applicants in California and fewer U.S. workers who take the jobs advertised there as compared to states like Wyoming or Colorado.

Many employers and associations expressed the view that U.S. workers are unwilling to perform this work due to the remote nature of the work rather than because of low wages, and some expressed disappointment with what they view as the unreliability of the few qualified U.S. workers who apply, stating that they often do not complete the work contract. Other commenters, such as the Utah Farm Bureau Federation, misunderstood the data in the proposal, and stated that the Department “concedes” that there are only 18 U.S. workers in range herding occupations because 18 U.S. workers were included in the 2014 SWA sheep herding surveys and worked in States with a statistically reportable wage. On the other hand, one SWA employee expressed the view that “[q]ualified job seekers often give low wages as one of the reasons they do not apply for these jobs, even though housing and meals are also provided. The number of U.S. job applicants has decreased over the past few years. Increased wages could help to encourage more worker interest in the jobs.” In addition, several employers noted that they have hired U.S. workers, with varying degrees of success. Further, one herding employer admitted that it could not attract U.S. workers because “Americans don’t like the conditions or low pay.”

Finally, some commenters also objected to the FLS-based AEW based on their view that it was inappropriate as a wage source for these occupations.²⁶ For example, the New Mexico Department of Agriculture and Wyoming Department of Workforce Services objected to the use of the FLS-based AEW on the view that the rate is based on “generic agricultural operations” and not specific to range herding. Similarly, Western Range and Mountain Plains expressed the view that the FLS is “a survey of aggregated farmworker positions except herders. Those positions pay by the hour, and do not provide housing or food, making those rates of pay completely inapposite to the range production of livestock.”

²⁴ See Seawolf, R., Fowler, J., & Schickedanz, J., *The Legacy of New Mexico Property Tax*, RITF Report 81 (Jan. 11, 2011), available at: http://aces.nmsu.edu/pubs/_ritf/RITF81.pdf.

²⁵ See Schulz, Lee, *Ag Decision Maker: Historic Hog and Lamb Prices*, File B2–10 (Feb. 2015), at Table 6, available at: <https://www.extension.iastate.edu/agdm/livestock/pdf/b2-10.pdf>.

²⁶ Some employers also objected to the proposed wage based on the misunderstanding that the proposal required payment for all hours worked and tracking of hours on the range.

Mountain Plains and Western Range asserted that the AEWR was a measure of “take home pay” from which U.S. agricultural employees need to pay a number of expenses not applicable to workers in these occupations. One herding employer stated that it has provided wage data on its workers for purposes of the FLS “for many years” but nevertheless objected to the FLS-based AEWR because, in its view, DOL had not properly consulted with USDA before proposing use of the FLS for these occupations and because H-2A workers receive additional “benefits” not paid to other workers. Siddoway Sheep stated that the use of the FLS-based AEWR was arbitrary because in its view shepherd wages have always been “well below average,” and instead asked DOL to conduct a comparison of the wage rate from the FLS with the monthly herding AEWR from a point “when adequate information regarding shepherders was available” and set the current wage based on that historic but, in their view, valid differential.

ii. Comments Supporting Use of the FLS-Based AEWR

We received only a few comments in support of the wage proposal in the NPRM, and most of the supportive comments were from individual commenters, including a former SWA employee responsible for surveys from the 1980s until 2005. We also received comments generally supporting the wage proposal from groups such as Public Citizen, a public interest group, and Western Watersheds Project, a project that works to protect and conserve the public lands of the American West. Most group comments, including the comment from Public Citizen, were undetailed and expressed only general support. These commenters asserted that the wage methodology was appropriate and necessary to protect against adverse effect on U.S. workers. Similarly, while he did not comment on the NPRM, Edward Tuddenham, an attorney representing workers, submitted a comment before publication that is part of the administrative record. That comment recommended either that workers be paid for a set estimate of hours multiplied by the FLS-based AEWR rate for time on the range and at the FLS-based AEWR for each hour spent in non-range work, or be paid the FLS-based AEWR for all hours actually worked regardless of location.

The Worker Advocates’ Joint Comment was by far the most detailed comment supporting the use of the FLS-based AEWR to set the monthly rate. That comment characterized using the FLS-based AEWR to set the monthly

rate as a “practical and commonsense approach.” However, this comment expressed the view that DOL’s use of a transition to the FLS-based AEWR in the proposed rule was misguided, and that requiring anything less than immediate implementation would have an adverse effect on U.S. workers performing work as ranch hands, who, like workers covered by this rule, may also perform work that is closely and directly related to the production of livestock.

This comment provided an analysis of purported data flaws in the SWA survey methodology and asked that DOL take into account the “immense losses” from prior SWA survey use to immediately implement the FLS-based AEWR as the base wage source. The comment attributed wage stagnation to DOL’s “outdated” methodology and to DOL’s settlement of various employer lawsuits over past wage increases, which in the commenters’ view has been “strongly pro-employer to the detriment of workers in this area and justifies immediate ameliorative action.”

In support of the view that the FLS-based AEWR should be immediately effective, the Worker Advocates’ Joint Comment pointed to several examples of jobs that, in their view, demonstrated that the ranching industry already supports workers earning the full FLS-based AEWR who perform similar work, particularly citing “Sheep, Farmworker General” in Wyoming, “Closed Range Herders” in Texas, and ranch hands performing livestock as well as other tasks. They further cited wage rates paid by employers “in states without large herder populations,” such as for Maine sheep farmers and sheep farm workers in North Dakota (both paid on an hourly basis). Further, they noted that California has a wage rate significantly higher than the current TEGL wages in other States. Finally, the commenters conclude “the sustained scarcity” of U.S. workers in these occupations:

is no doubt in large part a function of the fact that U.S. workers have the freedom to earn at least the federal minimum wage of \$7.25 per hour, which is substantially higher than the herder minimum wage.

Several of these commenters asked DOL to require payment for all hours worked, or at least for all hours worked when not on the range.²⁷ Western Watersheds asked that workers either be paid for all hours worked or not be required to work longer than the hours estimated by DOL. The Worker Advocates’ Joint Comment stated that workers should be paid the AEWR for

all hours worked while living “at or near the ranch,” based on the view that the exception to payment for all hours worked should be limited to the circumstances animating the FLSA exemption for this work, namely, that hours worked be extremely difficult to calculate. Edward Tuddenham similarly supported that workers should be paid for all hours at the ranch.

iii. Discussion and Decision—Change in Wage Rate

After reviewing all of the comments, we conclude that using the FLS-based AEWR to set the monthly wage for these occupations, which would triple the wage costs of many employers, is likely to result in adverse effect on U.S. workers by causing a substantial number of herding employers to close or significantly downsize their operations—leaving fewer herding jobs available to U.S. workers. Accordingly, we select a different wage source in this Final Rule, as discussed in greater detail below.

In reaching this conclusion, we do not base our analysis on a single comment or set of comments, but on the record as a whole, including data from budget documents submitted, reports from individual employers and associations, and historic pricing data. We recognize limitations on the data provided by employers, their associations, and their other supporters. For example, in some instances, employers used “labor costs” to attempt to demonstrate the impact of a wage increase, although labor costs may include more than just wages. In addition, enterprise budgets, which we examined carefully, typically include a line item for payment to the owner/operator, so that even with reduced or eliminated profits, there is still some payment to the owner. In addition, we cannot assume, as some commenters have done, that all labor in the enterprise budgets is paid at the TEGL wage levels. This is particularly true given that some H-2A employers noted in comments that they pay workers more than the current TEGL wages. We further recognize that only sparse data was provided on the impact of the proposed increase for cattle employers, which comprise a small subset of H-2A herding employers. However, despite these limitations, based on the size of the proposed increase and the data provided, the record provides a reasonable basis to conclude that the proposed wage increase is too great to be borne by the industry, and thus will result in adverse effect on U.S. workers

²⁷ A single employer also stated that an hourly wage would be appropriate during the shed lambing season.

because fewer herding jobs will be available.²⁸

As discussed further below, this Final Rule imposes a significant wage increase on the industry as compared to the current, stagnated wages required under the TEGLs, albeit of a magnitude lower than the wage originally proposed. However, for several reasons we disagree with worker advocates' comments that setting the wage based on anything other than the Farm Labor Survey is inconsistent with DOL's obligation to protect against adverse effect. First, although we acknowledge that wages under the SWA survey methodology have been stagnant for some time, we are concerned, based on the comments received, that the three-fold wage increase in the proposal would, if implemented, likely result in a significant number of employers choosing to down-size or close their herding operations, resulting in adverse impact on U.S. workers.²⁹ Second, although worker advocates cite in support of the proposed FLS-based wage other ranch jobs they view as similar and that are paid the FLS-based AEWR, those occupations do not appear to be primarily engaged in range work. To the extent that the worker advocates cited range jobs in Texas to support the proposition that ranchers overall can absorb a wage increase in the magnitude of the FLS-based AEWR, the data provided either reflects a prevailing wage rate significantly below the FLS-based AEWR or it is of such a small sample size to be unreportable under existing guidelines. In addition, we disagree with the suggestion that practices in sheep production "in states without large herder populations" and without range workers are relevant to the determination of whether employers using the current special procedures can

²⁸ Although the American Farm Bureau comment characterized the proposed wage increase with prices at the current levels as manageable, that is not determinative. We agree with the commenter that it is more reasonable to look to data assessing historic swings in prices. Examining those historic price swings helped guide our conclusion that adverse effect on U.S. workers likely would result from using the FLS-based AEWR.

²⁹ We note that in its analysis of the SWA survey data, the Worker Advocates' Joint Comment appeared to misunderstand data presented in the NPRM. The comment stated that in the NPRM, 80 FR at 20314, DOL "admitted" that surveys with results of between 18 and 30 workers were insufficient. However, the NPRM was discussing the total number of U.S. sheep herders identified in the SWA surveys with reportable results located in the mountain plains/western regions. This passage was not a discussion about the minimum sample size for any individual State. For these occupations, a survey of as few as six U.S. workers is consistent with the methodological requirements of ETA Handbook 385, provided a sufficient number of employers is represented by the sample.

absorb an increase of the scope proposed. Nor are we persuaded by the fact that some individual employers voluntarily provide higher wage rates than will be required under this Final Rule demonstrates that most employers will be able to absorb increases on the scale proposed. Third, we agree that the California sheep herding wage rates provide evidence that some employers can viably pay a higher wage, as discussed further below, but it does not support setting wage rates across the United States based on the FLS-based AEWR. Finally, we conclude that although we use a lower wage rate than is required for ranch hands, this will not have an adverse effect for U.S. workers similarly employed. As discussed in Sec. IV.A.2. in the preamble, we have further defined what work may be performed at the ranch under this Final Rule to prevent herders from being used to perform general ranch hand work. Given this protection, we conclude that the lower wage established for herders will not displace U.S. ranch hands.³⁰

We further decline to require payment of the FLS-based AEWR for all hours herders work while at the ranch. We note that this decision is consistent with the FLSA exemption, which permits the exemption to be taken for the entire year provided that the worker is "principally engaged in the range production of livestock." 29 U.S.C. 213(a)(6)(E). Given the limitation on duties that may be performed by range workers when they are working at the ranch as discussed in Sec. IVA.2., we conclude that this is not likely to have an adverse effect on U.S.

³⁰ Although we have decided not to use the FLS-based AEWR as the basis for the wage in this Final Rule, we must clarify the record with respect to two objections to its use for these occupations. First, we note that the FLS does, in fact, survey the wage of herding workers engaged in work on the range, though it is likely that, because there are few workers in these occupations, they may be a small portion of the sample in any State. Indeed, one herding employer expressly acknowledged that it reports its workers' wages to the FLS. In addition, while some commenters asserted that the FLS-based AEWR is inappropriate for range occupations because it fails to account for items such as meals, housing, transportation, workers' compensation, and work supplies, we note that (with the exception of meals), these items are also required to be provided without charge by H-2A employers paying the FLS-based AEWR and therefore do not support herding employers paying a lower wage. See 20 CFR 655.120(d)(1) (requiring housing to be provided to H-2A workers and any U.S. workers in corresponding employment not reasonably able to return to their residence within the same day); 20 CFR 655.120(e) (workers' compensation); 20 CFR 655.120(f) (tools, supplies, and equipment); 20 CFR 655.120(h) (governing transportation payment requirements). The reasons for applying these requirements throughout the H-2A program are set out in the 2010 H-2A rule, Temporary Agricultural Employment of H-2A Aliens in the United States, Final Rule, 75 FR 6884 (Feb. 12, 2010) and earlier H-2A regulations.

workers at the ranch because ranch hands can perform a much broader array of work duties. This is particularly true given that range sheep and goat herders have traditionally been granted certifications for a 364-day period to tend the herd throughout the production cycle, including times at the range and on the ranch. This practice is continued in this Final Rule, which specifically provides that it applies only to workers who spend more than 50 percent of the job order period working on the range, further distinguishing these workers from general ranch hands.

Finally, we decline to adopt Siddoway Sheep's suggestion that DOL conduct a comparison of the wage rate from the FLS with the TEGL wage from a point "when adequate information regarding sheepherders was available" and set the current wage based on that differential. In the absence of underlying records from historic SWA surveys, which are unavailable, we cannot pinpoint the year when adequate information may have been available. However, we reiterate that the TEGL wages have suffered significant stagnation when compared to the FLS-based AEWR for more than 20 years.³¹ Given this significant wage stagnation compared to other H-2A occupations, it is appropriate to require a wage rate under this Final Rule that is well above the TEGL levels in most states. As discussed below, this Final Rule accomplishes that result.

We are mindful of our statutory obligation to protect against adverse effect to U.S. workers, even in cases where the number of U.S. workers may be small. As a result, we are not persuaded by employer comments suggesting that U.S. workers will not be qualified or available for this work, regardless of the wage required.³²

³¹ For example, the Nevada TEGL wages were \$700 in 1994 and are currently \$800, an increase of approximately 14 percent over two decades. By comparison, the FLS-based AEWR for Nevada in 1994 was \$5.57 per hour, and the 2015 rate is \$11.37, a greater than 100 percent increase. Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States: 2015 Adverse Effect Wage Rates, 79 FR 75839 (Dec. 19, 2014); Whittaker, William G., Farm Labor: The Adverse Effect Wage Rate, CRS RL32861 (Apr. 14, 2005). Similarly, the 1994 sheep TEGL wage in Wyoming was \$700 and is currently \$750, an increase of approximately seven percent. By contrast, the hourly AEWR in Wyoming in 1994 was \$5.59 per hour in 1994, and is now \$11.14, nearly a 100 percent increase. *Id.*

³² Though several commenters viewed the data in the NPRM as evidence that DOL had "conceded" there were at most 18 U.S. workers in these occupations, this is a misinterpretation of the data. The 2014 survey identified 18 U.S. sheep herders among the States with a statistically reportable wage result located in mountain plains/western

Although we agree that the remoteness of the job and skills required are significant factors influencing availability of U.S. workers, it would be unreasonable to conclude that wages are without any influence on U.S. worker availability. As we have noted before with respect to our certification of temporary foreign workers, a basic principle of economic supply-and-demand theory is that in market economies, shortages signal that adjustments should be made to maintain equilibrium. Therefore, compensation should rise to attract more workers where employers are experiencing a shortage of available workers in a particular region or occupation. Wage increases may not occur as expected because of the availability of foreign workers for certain occupations, thus preventing the optimal allocation of labor in the market and dampening increased compensation that should result from the shortage.

The experience cited by Mountain Plains and Western Range in California (and by employers and others in other States)—that few U.S. workers are available for these jobs—does not undermine this basic economic theory for a number of reasons. First, we note that the Worker Advocates' Joint Comment indicated that some employers are using experience requirements as a basis to require references on letterhead of a previous employer. Such a requirement would be difficult for U.S. workers in many occupations, and this is even more true of U.S. workers seeking work in herding occupations.³³ In addition, though Mountain Plains and Western Range state that, in their experience, fewer U.S. workers apply for jobs in California than in other States even though the wage is higher in that State, the

regions of the United States. However, overall in 2012, 25 workers were included in surveys of sheep herders across those States. In addition, SWA surveys in other years included a higher number of workers, including in 2015. In 2015, 19 U.S. sheep herders were identified in SWA surveys across the mountain plains/western regions. In addition, because completion of the SWA survey is not mandatory, there are likely a significant number of additional U.S. workers not reported in the survey. For example, in California in 2015, the SWA survey included 10 U.S. sheep herders, and the SWA received a response from approximately 36 percent of sheep herding employers in the State. There are almost certainly additional U.S. workers among the remaining 64 percent of employers in that State. Finally, employers may have had an incentive to not report wages of U.S. workers in some circumstances because the TEGs permit a different (and often lower) State wage to be used in the event that the SWA survey did not report a wage finding.

³³ We have clarified in Sec. IV.B.2.A. of this preamble that such a written reference requirement cannot be imposed because it may result in U.S. workers who are otherwise qualified being rejected for work.

evidence they provide is contrary to the evidence from the SWA surveys, which suggest that higher wages in California may, in fact, be attracting greater numbers of U.S. sheep herders than in other states in the mountain plains/western regions of the United States. In fact, California is consistently among the states with the largest number of U.S. sheep herders identified in SWA surveys in these regions. In 2012, California had the largest number of sheep herders who were U.S. workers included in the SWA survey (10 in California out of 31 overall); in 2013, it was tied for the largest number of U.S. sheep herders in the SWA survey (13 in California out of 38 overall); in 2014, it was tied for the second largest number of U.S. sheep herders in the SWA survey (three out of 25 overall); and in 2015, it had the third largest number of U.S. sheep herders in the SWA survey (10 out of 52 overall).³⁴

Further, that the TEGL wages are higher than those H-2A workers could receive in their home countries should not have any bearing on the wage set by DOL. This will ordinarily be the case with foreign temporary workers. This fact supports, rather than refutes, DOL's obligation to require that wages are set at a rate that will not undercut the wages of U.S. workers, who have different economic incentives than foreign workers and must support themselves in this country, not abroad.

Finally, we have considered the commenters' anecdotal concerns about the unreliability of the domestic workforce. However, even if those concerns had been supported by more substantial evidence, the potential costs that may be incurred as a result of U.S. workers leaving before the end of the job order period are outweighed by the benefit to U.S. workers, and by our statutory responsibility to provide that U.S. workers continue to have access to these jobs.

c. Alternatives To Use of the FLS-Based AEWL To Set the Base Wage Rate

i. Comments on Alternatives

Where specific wage proposals were made by those opposed to using the FLS-based AEWL as part of the formula to set the base wage, these commenters generally either recommended that DOL not set any wage minimum for these

³⁴ In addition, the SWA surveys suggest that a significant percentage of California employers are hiring U.S. sheep herders. In 2012, approximately 13 percent (6/45) of sheep herding employers in California responding to the SWA survey hired at least one U.S. sheep herder; in 2013, that percentage was 16 percent (5/32); in 2014, that percentage was seven percent (2/29); and in 2015, that percentage was 13 percent (4/30).

occupations, that DOL continue to use the TEGL methodology, or that DOL adopt one of the two counter-proposals submitted jointly by the three primary employer associations (Mountain Plains, Western Range, and ASI), discussed further below. For example, several ranchers asserted that the federal government should have no role in setting wages for these occupations, but instead wages should be based on the agreement between the worker and employer based on the "market." Although some comments opposed any increase to current wage rates, many, including ASI and a number of individual employers, acknowledged that it was important for DOL to adopt a methodology to address wage stagnation in these industries.

Mountain Plains and Western Range recommended that DOL either set the monthly AEWL for these occupations based on an inflation-adjusted value from the 1994 sheep TEGL wages cited in the NPRM or based on the current FLSA minimum wage multiplied by a set estimate of hours, recommendations that were endorsed by ASI and a number of individual employers. This comment selected \$800/month as the appropriate wage to index, stating that it was the highest wage in the 1994 survey.³⁵ In support of using an inflation-adjusted TEGL methodology, the comment asserted that the single problem identified in the NPRM with the TEGL methodology was the lack of usable wage results from SWA surveys, which has resulted in wage stagnation. The comment further cited the 1994 sheep wage data cited in the NPRM as data identified by DOL "as the last year for which such surveys were conducted with statistically valid results." The comment clarified that its proposal would set a national rate for herders, except that if a State had a higher required rate, the State rate would apply. The associations justified a national rate on the basis that given that living expenses would be paid by the employer, differences in the cost of living in various states need not be considered.

For this approach, the associations recommended adjusting the 1994 TEGL wages using a capped version of the Bureau of Labor Statistics' Employment Cost Index for wages and salaries (ECI), with a three year transition followed by full implementation in year four.³⁶ The comment stated that the ECI is "the

³⁵ Arizona had the highest wage in 1994, and it was \$820/month. 80 FR at 20307.

³⁶ In a pre-NPRM comment submitted by ASI, Western Range, and Mountain Plains, the associations recommended using the ECI for total compensation and capping it at 2 percent.

most accurate measure of inflation in wages and salaries.”³⁷ The comment suggested that, in each year, the 1994 wage rate should be adjusted by 1.5 percent if the percentage increase in the ECI during the previous calendar year was less than 1.5 percent; by the percentage increase in the ECI if such percentage was between 1.5 percent and 2.5 percent, inclusive; or by 2.5 percent if the percentage increase in the ECI exceeded that amount.³⁸

As further support for this approach, the associations noted that the wage rate in 2019 under this recommendation, which would be above \$1,350 per month, would be consistent with the wage that one of the *Mendoza* plaintiffs stated in court filings would be acceptable in order to permit him to resume herding. The named plaintiff, Reymundo Mendoza, stated that he would “be willing to work as a herder if the employer paid \$1,300 to \$1,500 per month,” along with other benefits not required by this Final Rule, including paid vacation. Other plaintiffs in that litigation quoted higher rates necessary in order for them to return to herding, such as the minimum wage for all hours worked, or \$12.50 per hour. All of the plaintiffs in that action requested additional benefits in excess of those required by this Final Rule in order to resume herding.

The second alternative recommended by these associations, which was also endorsed by ASI and many individual employers, was to use the Federal minimum wage, multiplied by the estimate in the NPRM of 44 hours per week, to establish a monthly required wage. This alternative was also presented with a three-year transition period, with full implementation in year four. As with its first recommendation, if a higher State wage was required, it would apply. This comment states:

If DOL is determined to transition away from a survey-based monthly salary in favor of a monthly salary using the 44-hour week estimate and a base wage rate, Commenters submit that the Federal Minimum Wage of \$7.25/hour is a more reasonable starting point than the Farm Labor Survey based AEWs. . . . Since many of these herds and workers travel across state lines, because food, housing, and clothing are already

provided for free, and in order to create a more uniform process, Commenters would propose this single monthly rate in all states, except to the extent that the California or Oregon state statutes or judicial settlements require a higher rate already. While this will place a greater burden on employers in some states more than others, the FLSA wage rate applies uniformly across the nation and serves as a model for this proposal.

As with their first recommendation, the associations cited an affidavit from the *Mendoza* litigation, in which one of the plaintiffs stated that he would return to herding if a wage rate of \$1,300–1,500 per month, plus other benefits, was offered. As with their first proposal, the associations recommended use of the same ECI methodology to adjust future wage rates if DOL remained concerned about the potential for wage stagnation.

In addition to these two primary recommendations, two commenters suggested that DOL use the California herder wage to set wages in the program. An electric fencing supplier for commercial sheep ranches expressed the view that California’s wage “leads the trend” in wages and asked DOL to use California’s wage for all employers. The Chairman of ASI’s Legislative Action Council similarly stated that Oregon and California wages provided useful “reference” points. The Worker Advocates’ Joint Comment similarly used the California wage as evidence that herding employers could remain viable while paying a wage significantly above those currently required under the TEGLs.

Other commenters viewed the California wage rate less favorably. Without offering evidence in support, one individual employer stated that the higher California wage rate had been “detrimental” to the herding industry. Western Range and Mountain Plains asserted, again without evidence to support the assertion, that the California wage rate had forced employers to reduce the size of their businesses, hire fewer U.S. and foreign workers, and ask remaining workers to take on additional duties. These associations stated that proposed wage rates in the NPRM would be even more problematic because workers would be required to be paid significantly more but permitted to perform fewer duties.

We also received several alternate recommendations from individual commenters, which were not supported by other comments. One sheep herding employer stated its operation could afford a wage rate of up to \$2,500/month, although no methodology or data was provided in support of the \$2,500 figure. Based on the employer’s belief that U.S. workers will not apply

for herder jobs, another employer recommended that DOL set a higher wage rate for domestic workers as compared to foreign workers, stating that this “would address the Secretary’s statutory responsibility to consider the domestic workers without challenging the viability of the businesses offering employment.” Finally, a documentary filmmaker recommended that DOL compare the wage rates in States where large numbers of foreign workers abandon H–2A work with wage rates in States with lower levels of abandonment to determine the appropriate wage.

ii. Discussion of Alternatives and Decision To Use Federal Minimum Wage as Base

As discussed above, DOL received a number of comments asking DOL to retain the current TEGL methodology for setting wages or to let the market establish wage rates for these occupations. Neither of these recommendations is viable or consistent with the Department’s statutory obligation to protect against adverse effect on U.S. workers. As explained in detail above and in the NPRM, SWA surveys no longer provide sufficient information to permit DOL to use their results to set the AEW for these occupations, and the persistent lack of wage results has led to wage stagnation that may result in adverse effect to U.S. workers. Nor can the “market” set wages for these workers. The requirement that DOL protect against adverse effect is based on Congressional recognition that bringing in foreign labor has the potential to distort the market for these occupations, and a negotiation between a foreign worker with little bargaining power and a U.S. employer would invariably lead to a wage below what a U.S. worker would accept. For similar reasons, we will not base the wage rate in this Final Rule on whether wages are so low that even foreign workers abandon employment, because such a rate would still be substantially below that which a U.S. worker could be expected to accept. Further, we decline to adopt a two-tiered system by which U.S. workers must be offered a higher wage rate than that offered to foreign workers. To do so would disincentive the hiring of U.S. workers, and would institutionalize a second tier of foreign workers willing to accept wages below that required for U.S. workers, thus creating the adverse effect on U.S. workers we must avoid.

Further, the three primary employer associations have proposed setting the wage based on a methodology that will result in wages significantly above the current TEGL rates. The employer

³⁷ See, e.g., Russer, John W., The Employment Cost Index: What is it?, *Monthly Labor Review* (Sept. 2001), available at <http://www.bls.gov/opub/mlr/2001/09/art1full.pdf>.

³⁸ The commenters borrowed this formula from the W-agriculture visa program proposed in Section 2232 of the Border Security, Economic Opportunity, and Immigration Modernization Act, S. 744, 113th Congress (2013), passed by the Senate in 2013. The associations note that that program, including the wage rate applicable to that program, was the result of negotiations between employer representatives and farmworkers.

associations' proposals acknowledge that employers in livestock production can absorb a substantial wage increase, which we view as compelling evidence that the industry will remain viable even where employers pay a significantly higher wage rate to employees in these occupations. This acknowledgment is consistent with the fact that employers in Oregon and California are currently paying higher wages, and the industry remains viable at those rates in those States. This conclusion is further consistent with the historic pricing data provided by the Utah Governor's Office and American Farm Bureau, which, overall and considering variations from year to year, reflect that increases in the prices of livestock commodities (e.g., wool and lamb) have outpaced any increases wages.

For several reasons, we decline to adopt the associations' first recommendation to index the 1994 TEGL data. First, this recommendation was based on a mischaracterization of the 1994 TEGL data as the "last year for which such surveys were conducted with statistically valid results." The NPRM cited the 1994 TEGL data not because it was the last year that the SWA survey produced statistically valid results, but rather because it was the earliest year for which there was documented wage data when we published the NPRM.³⁹ In any event, the Department no longer has access to the underlying wage survey data for any of these historic wage rates to determine how many U.S. workers were included in any of these early surveys or otherwise assess their validity. Given that many commenters discuss the persistent lack of U.S. workers in these occupations for decades, and the absence of any data to assess an appropriate year and wage rate to index, we are concerned that continued reliance on the TEGL wages, even in indexed form, would be inconsistent with DOL's obligation to protect against adverse effect on U.S. workers.⁴⁰

In addition, we decline to adopt the alternate recommendations to use the California wage rate to set the national AEWR. We agree, despite differing opinions of some commenters, that the California and Oregon wage rates provide evidence that employers can afford a significantly higher wage rate for these occupations than is currently

paid, and can do so without job losses. Despite Mountain Plains and Western Range's assertion that the salary paid by California has led employers to reduce the number of U.S. and H-2A workers employed, this assertion not supported by any evidence. Labor certification data from 2013 and 2014 shows that California remains the second largest user of the herding special procedures. In any event, the California sheep herder wage rate is set through State law, Cal. Labor Code 2695.2(a)(2), and undoubtedly reflects local considerations that may not be appropriately applied across the other States where employing sheep, goat, and cattle herders typically are employed, which generally have lower wage rates than California.⁴¹

Instead, in view of the necessity to exercise our discretion in setting the wage rate, we view using the current Federal minimum wage rate of \$7.25 per hour (which will be adjusted annually based on the ECI), multiplied by an 48 hours per week, to be a more reasonable basis on which to set the AEWR for several reasons.⁴² First, we agree with the Joint Worker Advocates' Comment that the persistent lack of workers in these occupations is likely due in part to the fact that U.S. workers can earn at least the federal minimum wage elsewhere, so if the new herder wage at least meets the hourly Federal minimum wage, more U.S. workers will likely be available.⁴³ We further note that, although requesting additional non-wage benefits, three of the four *Mendoza* plaintiffs, all U.S. workers, stated that they would return to herding if offered either the wage that results from our methodology or the minimum wage rate (although one qualified that he was seeking the minimum wage for all hours worked). Second, we agree with Mountain Plains and Western Range that because many of these workers travel across State lines, and because most living expenses are required to be provided from the employer free of charge, a single national rate is appropriate, unless a higher State wage applies. We view the hourly wage requirement of the current Federal

minimum wage as the logical, non-arbitrary starting point on which to base the calculation of a national monthly wage rate, which sets the herder hourly wage no lower than the hourly minimum wage required for all other jobs in the U.S. economy is consistent with DOL's obligation to protect against adverse effect. Although \$7.25 for each hour worked is generally a floor, using the \$7.25 wage rate multiplied by 48 hours is reasonable in this circumstance because of the necessity of setting a monthly wage and because employers must provide housing and food without charge to workers in these occupations. Thus it is a reasonable exercise of DOL discretion and consistent with DOL's obligation to protect against adverse effect to set the wage rate as \$7.25 times 48 hours.

We are borrowing the current federal minimum wage rate for these occupations as the starting point for part of the new wage methodology, which will be indexed, as discussed below, and we do so with full recognition that workers "principally engaged in the range production of livestock" are not required to be paid the Federal minimum wage under 29 U.S.C. 213(a)(6)(E). We note that, in recommending use of the Federal minimum wage as the starting point for these calculations, the three primary employer associations and many individual commenters have accepted the use of this wage rate as appropriate for calculating the wage rate for these occupations. Further, it is clear from the legislative history that the exemption from the Federal minimum wage for these occupations is based not upon the wage rate itself, but rather on the remoteness of these occupations and the difficulty of tracking hours worked. See *Hodgson v. Elk Garden Corp.*, 482 F.2d 529, 531-33 (4th Cir. 1973); *Hodgson v. Mauldin*, 344 F. Supp. 302, 313 (N.D. Ala. 1972), *aff'd by Brennan v. Mauldin*, 478 F.2d 702 (5th Cir. 1973).

Therefore, using the \$7.25 per hour rate, multiplied by an approximation of hours to set a monthly salary, is consistent with the exemption or its purposes because it is not an hourly wage that requires hourly recordkeeping. This approach is also consistent with the way Oregon has interpreted its own State laws for these occupations, which requires the State minimum wage to be multiplied by a set number of hours (the equivalent of approximately 40 hours per week) to establish the herder's minimum required salary. Or. Rev. Stat.

³⁹ See <http://www.bls.gov/oes/current/oessrcst.htm>.

⁴⁰ The hourly calculation is discussed below.

⁴¹ Although they did not support the use of the Federal minimum wage to set the herder wage, the Worker Advocates' Joint Comment attributed the scarcity of U.S. workers in these occupations to the availability of the minimum wage in other occupations stating, "the sustained scarcity is no doubt in large part a function of the fact that U.S. workers have the freedom to earn at least the federal minimum wage of \$7.25 per hour, which is substantially higher than the herder minimum wage."

³⁹ Since publication of the NPRM, we have located additional data for 1990, and Vermillion and Midland submitted partial data for 1981 with their comments.

⁴⁰ We also view a single employer's statement that it could afford to pay \$2,500/month as an insufficient basis to set the AEWR at that rate.

653.020(1)(e), 653.010(9).⁴⁴ Similarly, the California monthly sheep herder wage is adjusted each time the State hourly minimum wage rises by the same percentage as the minimum wage increase. See Cal. Labor Code, § 2695.2(a)(2). The current California wage rate requires workers to be paid for the equivalent of approximately 41 hours per week based on the California minimum wage.

In order to prevent wage stagnation from again occurring, we have determined that the new base wage rate should be subject to an adjustment methodology. We agree with those commenters who recommended that we use the ECI for wages and salaries to address the potential for future wage stagnation. Our primary concern in setting the adjustment methodology for these occupations is to confirm that the wages for these occupations will continue to rise apace with wages across the U.S. economy. Although the Department has previously used the Consumer Price Index for All Urban Consumers (CPI-U) in other circumstances where adjustment for inflation is warranted, we conclude that it is reasonable to use the ECI for these occupations, given that housing and food must be provided by the employer under this Final Rule, making the cost of consumer goods less relevant than under circumstances in which workers are paying these costs themselves.

However, we decline to adopt the minimum and maximum ECI calculations provided by Western Range and Mountain Plains, which did not provide any economic rationale for the imposition of a cap, and we will instead use the uncapped ECI to adjust wages, beginning with the rate for calendar year 2017. The 1.5 percent minimum adjustment recommended by the employer associations is illusory, because the ECI has very rarely fallen below 1.5 percent since it was first used in 1981. On the other hand, the ECI has often been above 2.5 percent. Accordingly, the methodology recommended by the employer associations would typically be relevant only in circumstances where the ECI exceeds 2.5 percent. Placing a cap on the ECI-based adjustment has the potential to produce wage stagnation; thus, to protect against adverse effect to U.S. workers, we will not use a capped ECI to adjust wages because herders' wages should not be outpaced by changes to the wages of workers across

the U.S. economy in order to avoid adverse effect for U.S. workers.

d. Estimate of Number of Hours per Week That Herders Work

i. Comments on the Proposed Estimate of 44 Hours per Week

In order to set the monthly salary, the NPRM proposed a wage based on the estimate that herders work approximately 44 hours per week. This estimate was an average of the 40-hour-per-week estimate suggested by ASI, Western Range, and Mountain Plains, and the 48-hour-per-week calculation submitted by Edward Tuddenham, an attorney representing workers, both of which were submitted before publication of the NPRM. The 40-hour calculation submitted by the employer associations was based on the calculation in the *Zapata* settlement. The Tuddenham comment based the 48-hour calculation on estimates of hours submitted by employers on the Form ETA-9142A, which the comment characterized as a "conservative" estimate.⁴⁵ This comment stated that the 48-hour weighted average of employer-reported data from Form ETA-9142A is "the most diverse data set available" on the number of hours worked by herders. The data reported hourly estimates from the two primary employer associations, Mountain Plains (60 hours) and Western Range (40 hours), and is the only data source identified by any commenter that includes data collected across States.

Employers essentially agreed to the 44-hour estimate from the proposal. Although the pre-NPRM submission from Mountain Plains, Western Range, and ASI used a 40-hour calculation, Western Range and Mountain Plains used DOL's compromise 44-hour calculation in their comment submitted in response to the NPRM, and that proposal was endorsed by ASI and many commenters. We received no other concrete estimate of hours from employers or their representatives, nor did these commenters suggest an alternative data source for an estimation of herders' work hours. Employers generally stated that the exact number of hours varied based on a number of factors, such as seasons and weather. Where they did provide estimates of

⁴⁵ Tuddenham collected data from 195 applications for certification on which employers stated the number of hours per week that herders were expected to work. Data supplied in the Worker Advocates' Joint Comment replicated the Tuddenham analysis. Based on employer-reported hours on the Form ETA-9142A from sheep and goat herder applications filed between October 2013 and October 2014, the Worker Advocates' Joint Comment also concluded that the average number of worker hours was 48.

hours, they were imprecise (for example, stating that herders generally work 4–6 hours per day).

On the other hand, the Worker Advocates' Joint Comment objected to the 44-hour calculation from the proposal. While acknowledging that "a monthly AEWR based on average hourly totals will never be completely accurate," this comment pointed out that the 40-hour calculation from the *Zapata* settlement did not appear to be based on any judicial finding that workers are actually engaged in work 40 hours per week, but rather was likely calculated as a salary derived from a standard 40-hour workweek. They asserted further that employers have an incentive to under-report hours on the Form ETA-9142A in order to recruit workers, so that basing an hourly calculation on only employer-submitted data would be arbitrary and inconsistent with DOL's obligation to protect against adverse effect. In the commenters' view, DOL must therefore either directly survey workers or, if that is not feasible because gathering data from remotely-located employees is difficult, include data from existing worker surveys in establishing an estimate. Commenters cited only a single worker survey, *Overworked and Underpaid: H-2A Herders in Colorado*, conducted by Colorado Legal Services, in which Legal Services surveyed 90 H-2A Colorado sheep herders about their pay.⁴⁶ This study found that 62 percent of herders actively worked at least 81 hours per week. Two individual employers expressly disputed the methodology in the Colorado study, stating that it was not a reliable source and was based on biased questions from interviewers. In addition, a SWA employee commented that the 44-hour estimate was unrealistic given the requirement to be available up to 24 hours a day, seven days per week, but did not offer an alternative recommendation.

ii. Discussion and Decision To Use 48-Hour Week

Employers have been exempt from FLSA and H-2A recordkeeping requirements, so we agree with the Worker Advocates' Joint Comment that any estimate of hours worked will necessarily be imprecise. We further agree with the worker advocates that we should not base the hourly projection in any part (as we did in the NPRM) on the 40-hour estimate from the *Zapata* settlement. As discussed above, based

⁴⁶ The Colorado study was attached to the comment, and is also available online at <https://www.creighton.edu/fileadmin/user/StudentServices/MulticulturalAffairs/docs/OverworkedandUnderpaidReport.pdf>.

⁴⁴ See also Technical Assistance for Employers in Agriculture, available at http://www.oregon.gov/boli/TA/pages/t_faqs_taagric.aspx.

on data supplied in comments, employers across States have indicated through their Form ETA-9142A filings that herders work on average 48 hours, and so it would be improper to require them to pay for fewer hours.

We concur with the assessment from Edward Tuddenham that the 48-hour estimate from ETA's own data is based on the most comprehensive and detailed data source from which to establish an hourly calculation. Accordingly, we will use that 48-hour calculation, which was also replicated in the submission by the Worker Advocates' Joint Comment, to set the number of hours for the monthly salary formula. Given the challenges with collecting data for these occupations, we conclude that it would be very difficult and resource-intensive for DOL to collect from sources outside ETA data on hours worked. Further, the Colorado study on herder wages, hours and working conditions submitted by worker advocates is informative, but very limited because it is data from a single State and thus not representative of the industry as a whole. Finally, we disagree that employers are likely to under-report hours on the Form ETA-9142A to make the job appear more attractive because employers already advertise in their job orders that herders must be available up to 24 hours per day, 7 days per week.

We recognize that this 48-hour estimate will result in a higher wage than the industry-consensus proposal. However, we conclude that requiring payment for four hours a week in excess of the calculation proposed by the primary employer associations, and supported by many employers, is unlikely to have a substantial effect on the ability of employers to absorb the wage increase required by this Final Rule. Moreover, we conclude that, because it more accurately reflects the likely actual hours worked, it also more accurately reflects the wage that will prevent adverse effects on U.S. workers. Indeed, it would be inconsistent with DOL's obligation to protect against adverse effect to allow employers to pay for fewer hours than is indicated on their own Form ETA-9142A.

e. Food Deductions

i. Comments

In the NPRM, we invited comment on the issue of whether employers should be permitted to deduct some food costs from the required wage rate "in light of the proposed increase in wages," and, if a food deduction was to be permitted, the appropriate amount of the deduction. 80 FR at 20305. Under the standard H-2A program regulations,

employers are permitted to deduct the actual cost of meals up to a rate set each year (which is annually adjusted based on the CPI-U) to offset costs for providing the worker with three meals, unless a higher amount is authorized by the Certifying Officer. 20 CFR 655.173. The maximum standard deduction is currently \$11.86 per day (\$355.80 for a 30-day month). *Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States: 2015 Allowable Charges for Agricultural Workers' Meals and Travel Subsistence Reimbursement, Including Lodging*, Notice, 80 FR 9482 (Feb. 23, 2015).

Under both of the primary wage recommendations from Mountain Plains and Western Range, employers would be responsible for paying for food, which is consistent with the NPRM, the existing sheep and goat herding TEGL, and the current cattle wage rates. But while neither of these recommendations proposed a food deduction, Mountain Plains and Western Range "encourage[d] the Department to consider permitting one, or at least permitting a deduction reflecting the difference between the more extensive and more expensive food provided to these workers compared to the subsistence and meal charges that the Department uses for other workers." These commenters stated that both the California State wage and the *Zapata* settlement in Oregon permit employers to take a food credit.

In addition, Mountain Plains and Western Range asked DOL to consider the pre-NPRM letter from these associations (and also from ASI) in addition to the two new proposals in its comment. That pre-NPRM letter, included in the administrative record, asked DOL to set the wage rate at the FLSA minimum wage multiplied by 40 hours with a deduction for food based on the USDA "liberal" meal plan for a male, aged 19-50 years, which they stated would "best reflect the protein-rich diet appropriate for active young to middle-aged men working outdoors in high-altitude environments."⁴⁷ The pre-NPRM letter also requested that the 20 percent increase for a single individual—rather than a family—in the USDA plan be used, even though, in most instances, the employer would be purchasing food for multiple workers.⁴⁸

⁴⁷ See Official USDA Food Plans: Cost of Food at Home at Four Levels, U.S. Average, April 2015, available at <http://www.cnpp.usda.gov/sites/default/files/CostofFoodApr2015.pdf>.

⁴⁸ Under the USDA plan, the costs given are for individuals in 4-person families. For individuals in other size families, the following adjustments are suggested: 1-person—add 20 percent; 2-person—

Based on the April 2015 USDA release, the permissible deduction under this proposal would be \$448.80 per month.

Other employers and associations supported some type of food deduction. For example, the comment from Siddoway Sheep suggested three alternatives for food deductions: (1) Deducting the cost of purchasing food on each employee's grocery list from that employee's wages, (2) a standard ranch-specific deduction based on annualized actual expenditures from the prior three year period,⁴⁹ or (3) a standard industry-wide deduction equal to 128 percent of the liberal USDA Food Plan Cost, which the employer states is "comparable to the actual amount that we spend on meals." This employer stated that workers sometimes waste food and that requiring workers to pay for food might reduce this incentive. Other commenters, including the Wyoming Farm Bureau Federation, offered more general support for the concept that either food costs should be deducted or wages should be set at a level that reflects employer costs, including food and housing.

Vermillion and Midland stated that a food deduction should be permitted for several reasons. The employers cited two legal "precedents" for its position that a food deduction should be allowed, an administrative case⁵⁰ and Section 3(m) of the FLSA, 29 U.S.C. 203(m), which generally permits deduction of the "reasonable cost" of "board, lodging, or other facilities, if such board, lodging, or other facilities are customarily furnished by the employer to his employees." 29 CFR 531.2.⁵¹ The Wyoming Farm Bureau Federation and an individual employer asked DOL to clarify that employers were not required to pay for items like soda and tobacco.

add 10 percent; 3-person—add 5 percent; 4-person—no adjustment; 5- or 6-person—subtract 5 percent; 7- (or more) person—subtract 10 percent. To calculate overall household food costs, (1) adjust food costs for each person in household and then (2) sum these adjusted food costs. See footnote directly above.

⁴⁹ The comment cited two different amounts for its cost per worker: \$476 per worker per month and \$467 per month.

⁵⁰ *In the Matter of Western Range Association*, 95-TLC-4 and 5 (1995).

⁵¹ In addition, this comment stated that SWA surveys demonstrated that whether meals are required to be provided has a significant impact on the wage rate, stating that the 2010 Wyoming range rate was \$1600, with deduction of board permitted, but in 2013, it was \$875 with board required to be provided free of charge. We note that this change was actually based on a change in the State that was used to set the wage rate. The 2010 survey was based on a Wyoming survey, while the wage rate was later based on the Colorado survey due to insufficient data in a later year.

On the other hand, several individual employers opposed a food deduction. For example, one noted that payment of food by the employer is a “longstanding practice of the industry.” Another stated that it would be difficult to calculate the cost of food provided to an individual worker when food is delivered to a sheep camp containing multiple workers. Similarly, the Worker Advocates’ Joint Comment stated that food deductions should be permitted only if employers paid the full FLS-based AEWR required by the proposal at the end of the transition period, reasoning that once the wages of these workers were aligned with the wages in the rest of the H–2A program, the workers could afford their own food. This comment recommended that the deduction be limited to the ordinary H–2A wage deduction. The Western Watersheds Project opposed any food deductions.

ii. Discussion

This Final Rule maintains the current practice under the TEGs for these industries, and does not permit employers to deduct the cost of food from workers’ wages. The decision to use the \$7.25 per hour rather than the full FLS-based AEWR, we think it is reasonable to disallow deduction from wages for the costs of providing food to these workers. This is particularly true given that sheep and goat herding employers have continually been required under the TEGs to provide food without cost to the workers, and cattle herding employers have been required to pay these costs due to the wage finding in the SWA survey since 2013. In addition, as the pre-NPRM comment from ASI, Western Range, and Mountain Plains demonstrates, in adopting a lower base wage rate than the FLS-based AEWR, a food deduction would prevent DOL from fully addressing the wage stagnation in these occupations. Allowing a food deduction would offset a substantial amount of the benefit to the workers of the increase in the wage rate and result in setting effective wages not significantly above the rates required two decades ago.

The legal precedents cited by commenters do not suggest a different result. The administrative case cited by Vermillion and Midland only states that those employers providing meals without charge should be separately surveyed from those that do not, but takes no position on whether a food deduction should or should not be permitted. Further, Section 3(m) of the FLSA applies only where the FLSA applies. Although a few commenters stated that California law permits a food

deduction from its sheep herder wage, this is incorrect. California Industrial Welfare Commission (IWC) Order No. 14–2001, Sec. 4(E), 10(F) (amended Jan., 1 2002) expressly bars employers of sheep herders from offsetting the required wage by meals or lodging and incorporates by reference the requirement under the H–2A special procedures for employers to pay for meals.⁵² In addition, Oregon does not appear to authorize a food deduction for workers exempt from the minimum wage. Or. Rev. Stat. §§ 653.020(1)(e), 653.010(9).⁵³

As discussed above, applying a food deduction would substantially erode the wage increases in this Final Rule after decades of wage stagnation, and is therefore inconsistent with DOL’s statutory obligation under the INA. Finally, in response to comments, we clarify that the employer is only required to pay for sufficient and adequate food, and water, as discussed in Sections IV.B. and E. in the preamble related to §§ 655.210(e) and 655.235, and is not required to provide workers with other items, such as tobacco or soda, free of charge, although the employer is free to do so.

f. The Transition Period

i. Comments

Given the size of the wage increase in the NPRM, we proposed a four-year transition with full implementation in year five. 80 FR at 20310. Under the proposal, wages would have been set at 60 percent of the full wage rate in year one, 70 percent in year two, 80 percent in year three, and 90 percent in year four. In proposing this approach in the NPRM, we reasoned that a transition period was needed in order to avoid the unintended consequence of significant job losses that could be prevented by a gradual implementation.

Both the primary Mountain Plains and Western Range recommendations supported a transition, mirroring DOL’s concerns in the NPRM about significant job losses if the wage increase were implemented immediately. For each proposal, Mountain Plains and Western Range recommended a three-year transition, with full implementation in year four. For their proposal to use an indexed TEG wage rate, they proposed to start at 80 percent of the fully adjusted wage; for their proposal to use

the FLSA minimum wage, they proposed to start at 75 percent of the adjusted wage. The comment did not provide for any inflation adjustments to the FLSA-based wage until after full implementation, and did not explain the basis of that recommendation. Several individual employers and associations, including the Colorado Wool Growers Association, asked for a longer transition period than proposed if the FLS-based AEWR was used to establish the monthly rate.

Conversely, the Worker Advocates’ Joint Comment stated that a transition to a new wage could not be squared with DOL’s statutory obligation to protect against adverse effect. This comment asserted that no transition of new wage rates was appropriate given the long history of wage stagnation, which, as discussed above, they attributed to DOL’s policy of using SWA survey results and implementation of those results. As discussed above, they cited wage rates for several occupations that do not primarily involve range work, were below the FLS-based AEWR, or were based on sample sizes too small for the SWA to report a wage. They also cited the current California sheep herder wage rate for the proposition that employers could immediately adjust to the full FLS-based AEWR. This comment stated that a transition would cause adverse effect to U.S. workers employed as ranch hands by permitting a much lower wage to be paid for similar work. It further asserted that DOL provided no “empirical support” for the need for a transition in the NPRM, and asked DOL to consider the scope of previous wage stagnation from the SWA surveys as the basis to reject any transition period, or at least in deciding what percentage level to set the wage during a transition period. Several other comments from the Western Watersheds Projects and a few individual commenters stated, without additional elaboration, that the proposed wage rates should apply immediately.

ii. Discussion

The wage increase under this Final Rule is less than under the proposal, but it remains significant; the final wage rate approximately doubles the current required wage rate for sheep herders in a number of States. For the reasons discussed above, consistent with our decision to use an alternative to the FLS-based AEWR to set the monthly AEWR, we conclude that the data submitted in the Worker Advocates’ Joint Comment does not require immediate implementation of the new wage. Although the California wage

⁵² Available at: <http://www.dir.ca.gov/Iwc/IWCArticle14.pdf>; see also State of California, Department of Industrial Relations: Minimum Wage FAQ, available at http://www.dir.ca.gov/dlse/faq_minimumwage.htm.

⁵³ See also Technical Assistance for Employers in Agriculture, available at http://www.oregon.gov/boli/TA/pages/t_faq_taagric.aspx.

provides some evidence that a higher wage can be tolerated, we note that the current California rate was implemented over a number of years, and therefore does not provide strong evidence that employers outside of California can absorb a significant increase quickly without job losses.⁵⁴ As discussed above, we disagree with several of the conclusions raised by the Worker Advocates' Joint Comment about DOL's conduct in administering the SWA surveys, but agree that the lack of wage results from U.S. workers in the surveys has led to wage stagnation for these occupations.

In light of the scope of the increase and the economic data provided by commenters, we conclude that a limited transition period to the new wage is necessary. However, we recognize that any transition must not be longer than necessary to prevent adverse effect. As a result, this Final Rule requires a two-year transition (rather than the four years proposed, or the three years recommended by Mountain Plains and Western Range) with full implementation in year three. A transition is particularly needed given that the new wage rate must be paid by all employers one month after publication of the Final Rule, even if the employer is operating under a current certification, as provided in the discussion above related to paragraph 655.211(a). In addition, consistent with the consensus proposal submitted by Mountain Plains and Western Range, we will require the wages to be set at higher percentage levels during the transition years than those proposed, with 80 percent of the full wage rate required in year one and 90 percent in year two. This methodology requires employers to pay more than half of the required increase in the first year of implementation.

The Western Range and Mountain Plains proposal did not apply any inflation adjustment until after the transition period in their proposal. We conclude that this is inconsistent with DOL's obligation to protect against adverse effect, because it would result in wage rates in future years being lower than if no transition had been applied. Accordingly, after setting the wage rate in year one, we will begin to apply the ECI adjustment in year two so that

wages in future years will not be reduced by DOL's decision to apply a transition period.

D. Filing, Processing and Post-Acceptance Procedures

1. Sec. 655.215 Procedures for Filing Herding and Range Livestock Applications

a. Geographic Scope, Who May File, What To File

The TEGLs provide a variance from the geographic scope limitations applicable to *Applications for Temporary Employment Certification* filed under the standard H-2A regulations, specifically the geographic limitations of 20 CFR 655.132(a) for H-2ALCs and 20 CFR 655.131(b) for master applications. The variance set out in the TEGLs permits an employer (whether an individual, an association, or an H-2A Labor Contractor) engaged in range herding or livestock production to file an application and Form ETA-790 covering work locations in multiple areas of intended employment and within one or more States. The TEGLs require those employers to include an attachment listing the locations, estimated start and end dates, and the names and contact information of all employers where work will be performed under the job order when filing an *H-2A Application for Temporary Employment Certification*. Employers are expected to identify the locations with as much geographic specificity as possible in order to apprise potential U.S. workers of where the work will be performed and to ensure recruitment in all areas of intended employment. The NPRM proposed continuing the TEGLs' approach to the geographic scope of work permitted in *Applications for Temporary Employment Certification*, which would allow applications for both range herding and production of livestock positions to encompass work in multiple areas of intended employment and in more than two contiguous States, and require the employer to submit a work location list with its application.

The Department did not receive any comments directly addressing the proposal related to geographic scope limitations for job orders and applications. However, we continue to recognize the transient nature of range herding and livestock production work, as was apparent in other comments received and has been long recognized by the Department. Accordingly, we have adopted this provision in the Final Rule without change.

For master applications, the TEGL covering sheep and goat herding range workers, but not the TEGL for range livestock production workers, allows an association filing as a joint-employer with its members to submit annually a single Form ETA-790 for a master job order directly with the NPC that identifies all included employer-members, dates of work, and work locations and will remain open year-round, unless modifications are required. The employer-members included in the sheep or goat herding master job order are not required to have the same date of need, which is a variance from the date of need requirement in the standard H-2A regulations, at 20 CFR 655.131(b). Because the TEGL covering range workers engaged in livestock production does not include this variance, an agricultural association filing a master application seeking range livestock production workers must submit a new Form ETA-790 to the appropriate SWA in advance of filing each *H-2A Application for Temporary Employment Certification*, and that job order may only include employer-members who share the same date of need. In the NPRM, we proposed to allow an agricultural association filing a master application for a range occupation eligible for processing under these rules to include employer-members with different dates of need in a single application and job order. This proposal would expand current practice for sheep and goat herding employers to livestock production employers. We also proposed to retain as a variance only for sheep and goat herding positions the allowance for an association to submit a single Form ETA-790 for a master job order annually.

The Department did not receive comments addressing the filing procedures in proposed § 655.215, and we adopt the provision largely as proposed. Specifically, the Final Rule adopts without change the proposed provisions identifying the forms and documents range employers must submit to the NPC and allowing employer-members with different dates of need to be included in a single master application, regardless of whether the job order and application involves range sheep or goat herding or other range livestock production. The Final Rule also adopts without change the provision allowing annual submission of Form ETA-790 for master application job orders for range sheep and goat herding occupations, unless the job order requires modification. We conclude that these filing procedures

⁵⁴ The California wage rate was first established in 2001 at a rate of \$1050 per month. See California IWC Order No. 14-2001, Sec. 4(E). Adjustments are now made to the California monthly sheep herder wage rate each time the State hourly minimum wage increases (with the monthly wage increased by the same percentage as the State hourly minimum wage increase). Cal. Lab. Code 2695.2(a)(2).

will increase consistency of processing job orders and applications for range occupations. For greater clarity, however, we have made a minor deletion from proposed § 655.215(b)(2); we have removed the word “total” in both places that it appeared in this provision regarding the period of need identified on an *H-2A Application for Temporary Employment Certification* and Form ETA-790 submitted for processing. The dates of need identified on all *Applications for Temporary Employment Certification* and job orders must be continuous, making the “total” term unnecessary.

As we have stated above, this section of the Final Rule contains the only variances the Department is making from the general H-2A filing procedures for eligible employers seeking workers in range herding and production of livestock occupations. Unless specifically addressed in these provisions, employers must comply with the processing procedures in the standard H-2A regulations, at 20 CFR 655.130–655.132.

b. Period of Need

i. Background

The range livestock production TEGL does not address the period of need an employer must identify on its *H-2A Application for Temporary Employment Certification*. As a result, these employers must demonstrate that the period of need identified on the application satisfies the temporary, seasonal need standard in the standard H-2A regulations, at 20 CFR 655.103(d). The range sheep and goat herding TEGL, however, permits an employer seeking temporary range sheep or goat herders to identify a period of need of up to 364 days and provides for year-round posting of master job orders.

The NPRM proposed continuing the TEGLs’ distinction between sheep and goat herder employers’ period of need and the period of need allowed for the range production of livestock. Thus, the NPRM proposed allowing employers of range sheep and goat herders to identify a period of need of up to 364 days on the *H-2A Application for Temporary Employment Certification* and for the Form ETA-790 for a master job order to be submitted once annually. In addition, the NPRM proposed allowing employers of range livestock production workers to identify a period of need of up to 10 months and proposed to require a separate, application-specific Form ETA-790, including those associated with master applications, to be filed with each *H-2A Application for Temporary Employment Certification*,

Form ETA-9142A, as described in proposed §§ 655.205 and 655.215. Also as set out in the NPRM, the proposed continuation of this distinction between range occupations for the purposes of the period of need was intended to maintain overall consistency with the standard H-2A regulations, at 20 CFR 655.103(d), and at the same time preserve the unique history of and experience with range sheep and goat production employers.

The NPRM sought comment specifically on the issue of the temporary and seasonal nature of herder work, including the amount of time spent on the open range during a year. 80 FR at 20311. We asked about whether the unique characteristics of herding work exist year-round. *Id.* Specifically, we sought comment about “whether sheep and goat herding involve distinct temporary positions at different times of the year that require more than one certification to reflect distinct temporary and/or seasonal needs under the INA.” 80 FR at 20303. The NPRM noted that we would consider the application of a similar 10-month limitation to sheep and goat herders, to reflect more appropriately their temporary or seasonal need as required by the INA. *Id.* We asked several specific questions about seasonal or cyclical variations in herder work, worktime spent on the range versus the ranch, and duties performed during the different periods, among other questions. 80 FR at 20303.

ii. Comments on Temporary Need

Many comments by employers of sheep and goat herders indicate that they use the 364-day maximum period of need permitted under current practice. Several employer comments indicate that they re-employ the same H-2A workers over the years. Mountain Plains and Western Range urged the retention of the 364-day limit on sheep and goat herding, and suggested the extension of the cattle herding limit from 10 to 12 months, because “[a]ll of these animals require year-round care[.]” However, this comment was somewhat vague about any particular seasonal demands of the work:

The general response [to the NPRM questions about the seasonal nature of the work] is that the work is performed on an “as the need arises” basis, and there is no single description of a worker’s typical day. The work is defined first and foremost by the needs of the animals in the herder’s care. During lambing, kidding, and calving season, the days are longer and the work is focused on the healthy birthing of new animals. Those duties occur at certain times of the year according to the natural cycles of the seasons and the animals. In parts of the West, employers use fixed structures (known as

“sheds”) to keep livestock and their offspring safe and healthy during the birthing process. Other ranches perform birthing in open-air pastures. The amount of time spent assisting with this phase depends on the natural conditions of the male and female livestock.

The associations explain that the work is not only performed on an “as needed” basis, but it is also highly dependent on the weather conditions.

The Worker Advocates’ Joint Comment included a brief statement supporting separate certifications for the range production of sheep and goats over the 364-day period of need:

We applaud DOL for requesting comments on whether more than one H-2A labor certification period should be necessary for workers who tend sheep and herd goats. The best way to protect the wages and working conditions of U.S. workers is to have two separate certification periods, one for the birthing period in the spring, which takes place on the ranch, and one for the open range season which lasts from summer through winter. Because the spring birthing period involves no open range tasks, jobs during this season should fall under the normal H-2A regulations, not the proposed special regulations for open range herders.

One of the most informative comments on the nature of herder work and its seasonality was from Siddoway Sheep Company. This comment clearly delineated the seasonal aspects of herder work, at least with respect to this particular ranch. In the winter, the work on the ranch is devoted to lambing (some ranches conduct lambing operations later in the spring, sometimes on the open range, and others conduct it in sheds on or by the base ranch). The Siddoway Ranch conducts lambing in sheds. In January, herders bring the flock closer to the base ranch, and as the herders move down from the winter range, they move into the bunkhouse. Lambing begins in mid-February. Workers are engaged in lambing activities at the base ranch for eight to ten weeks. During the next season—spring grazing—herders move into mobile housing, also called a “sheep camp.” During the spring grazing season, herders move the sheep away from the base ranch toward the summer range, and this period lasts for eight to ten weeks. By the first day of summer, the herders begin to move the sheep to the high mountain meadows for summer grazing. During summer grazing, herders move from the “sheep camps” into outfitter tents. By mid-September, herders begin to move the sheep down from the mountains for fall grazing, and to separate the market sheep from the rest of the herd. The herders move back into the sheep camps. The sheep are bred in October, during the fall grazing period. Once the

sheep are bred, the herders and the flock return to the base camp for the winter. The lambing preparations begin again in January. According to Siddoway's practice, the fall grazing period, which is approximately 20 weeks, is the least labor intensive and is the best time for employees to return to their home abroad or otherwise take an extended vacation.

iii. Discussion

We have decided to retain the limitations on period of need contained in the TEGLs and proposed in the NPRM. As a result, § 655.215(b)(2) requires that the period of need for the range production of cattle must be no more than ten months, which is consistent generally with the standard H-2A maximum period of need, and the period of need for range production of sheep and goats must be no longer than 364 days.

We make this decision after considering several factors. First, Section 101(a)(15)(H)(ii)(a) of the INA permits aliens to obtain H-2A visas to come "temporarily to the United States to perform agricultural labor or services . . . of a temporary or seasonal nature." 8 U.S.C. 1101(a)(15)(H)(ii)(a). Section 101 does not define "temporary" work for purposes of H-2A visas, nor does it indicate how long a position may last and still qualify as "temporary" work. The legislative history of the INA is silent about the expected duration of "temporary" work. Under current regulations issued by the U.S. Citizenship and Immigration Services (USCIS), a component of the Department of Homeland Security (DHS), in order to obtain an H-2A visa, an employer must establish that employment is either seasonal or temporary, which, except in extraordinary circumstances, should last no longer than one year. 8 CFR 214.2(h)(5)(iv)(a). DOL's H-2A regulation on this point is consistent with the DHS regulation. 20 CFR 655.103(d). Therefore, neither the statute nor the agencies' regulations proscribe the 364-day period of need applicable to the range production of sheep and goats.

Second, we have relied for decades on the unique history and experience of sheep herding in the U.S. to support the 364-day period of need for sheep ranchers. This history was discussed in great detail in both the NPRM, 80 FR at 20301-20302, and the TEGL governing sheep and goat production, and we see no reason to rescind our reliance on this aspect of these jobs to shorten the period of need.

Finally, we have reviewed and considered all the comments on this subject, and it is clear that both the ranchers and the herders they employ are well accustomed to the longer period of need for range production of sheep and goats, and that shortening it would be disruptive to the livelihoods of employers and employees alike.

c. Comments on Filing Procedures Addressing Issues Outside the Scope of the Rulemaking

We received several comments on post-certification procedures that were beyond the scope of this rulemaking. First, Mountain Plains and Western Range requested clarification about the post-certification ability of an agricultural association filing a master application to transfer workers between employer-members as needed during the certified period. Similarly, Eph Jensen Livestock, LLC also commented on the value of an association's ability to transfer workers among employer-members on a master application job order. As the Mountain Plains and Western Range comment pointed out, the INA allows a master application certified under the H-2A program to be used for the job opportunities of any of the employer-members that were disclosed in the master job order, and hired workers may be transferred among the employer-members to perform the services for which the certification was granted. 8 U.S.C. 1188(d)(2). This statutory authority, which has not changed, applies to all master applications filed under the H-2A program, not only those for range sheep and goat herders. Although the range sheep and goat herding TEGL included discussion of this INA provision, and explained the Department's expectations where an agricultural association engages in worker transfers, the allowance is not a variance from standard rules. As it is not a variance applicable only to the applications eligible for filing under the herding and range livestock regulations, it is outside the scope of this rulemaking.

The Department also received comments from two employers, Maltberger Ranch and Cherry Ranch, suggesting changes to H-2A visa duration and the Department's general processing timeline for H-2A applications. McPherrin Damboriena Sheep Co. also expressed the difficulty of aligning visas with actual employment dates. The Department considers these comments beyond the scope of the proposed rule, because they raise issues that cannot be resolved through this regulatory process, which addresses only H-2A range

applications, and are therefore not within the scope of this rule.

2. Section 655.220—Processing Herding and Range Livestock Applications for Temporary Employment Certification

The TEGLs do not provide variances from the processing procedures in the standard H-2A regulations at 20 CFR 655.140-655.145, except as necessary to accommodate the variances provided for master job orders for range sheep and goat herding occupations, which are submitted annually to the NPC and posted with the SWA year-round, unlike other job orders. Because the Department proposed in the NPRM to shift the timing and location of filing the Form ETA-790 for range occupation job orders from a pre-filing submission to the SWA to concurrent filing to the NPC, we also proposed variations to the standard processing procedures to the extent necessary to reflect the NPC's processing of Forms ETA-790 received with *Applications for Temporary Employment Certification* for these occupations. The Department proposed that, when the Certifying Officer (CO) determines that an application and job order meet all regulatory requirements, the CO would notify the employer and transmit a copy of the Form ETA-790 to any one of the SWAs with jurisdiction over the anticipated worksites so that recruitment can begin. When an agricultural association filed a master application and Form ETA-790 on behalf of its employer-members, the NPRM proposed the CO would transmit a copy of the Form ETA-790 to the SWA with jurisdiction over the association's location. The CO's notification would also direct the SWA receiving the Form ETA-790 copy to place the job order promptly in intrastate and interstate clearance, including forwarding the application to all States where work will be performed.

In addition, the NPRM included a proposed provision intended to clarify how the electronic job registry requirement at 20 CFR 655.144(b) (*i.e.*, H-2A job orders must be posted in OFLC's electronic job registry until 50 percent of the work contract period has elapsed) would apply to a job order approved for an agricultural association filing a master application, given the different dates of need the NPRM proposed be permitted for individual employer-members within a single master job order. Specifically, the Department proposed that we would keep the master job order posted on the electronic job registry until 50 percent of the work contract period had elapsed for all employer-members identified on the job order (*i.e.*, the 50 percent period

would be measured based on the employer-member with the last date of need).

The Department did not receive comments addressing these proposed provisions, and we are adopting them unchanged in the Final Rule. These provisions establish a clear, consistent processing framework for applications and job orders for eligible range employers. This section of the Final Rule contains the only variances the Department is making from the general H-2A processing procedures for eligible employers seeking workers in range herding and production of livestock occupations. Unless specifically addressed in these provisions, employers must comply, as they do currently, with the processing procedures in 20 CFR 655.140–655.145.

3. Section 655.225—Post-Acceptance Requirements for Herding and Range Livestock

The TEGL for range livestock production occupations provides no variances from the standard rule's post-acceptance procedures in the standard H-2A regulations, at 20 CFR 655.150–655.158. The TEGL for range sheep and goat herding occupations, however, provides a variance from the newspaper advertisement requirement in the standard H-2A regulations, at 20 CFR 655.151, and clarifies the Department's expectations for an agricultural association's handling of referrals and U.S. applicants responding to master job orders involving multiple employer-members.

In the NPRM, the Department proposed to expand almost all of the range sheep and goat herding TEGL's variances to encompass range livestock production occupations as well. The proposed rule waived the requirement for the placement of an advertisement on two separate days in a newspaper of general circulation as provided in the standard H-2A regulations, at 20 CFR 655.151. The NPRM also included a proposed provision intended to clarify that master application job orders for herding and range livestock employers would be handled in the same way OFLC handles other job orders approved for an association of agricultural employers filing a master application as a joint employer on behalf of its employer-members; the CO would direct the SWAs to keep the job order on its active file until 50 percent of the period of the work contract has elapsed for all employer-members identified on the approved job order. Moreover, the NPRM proposed to expand and codify an association's obligation to accommodate U.S. workers' worksite

location preference to all master job orders for range occupations eligible for processing under this rule. Finally, the NPRM included a proposed provision intended to clarify that an association handling the recruitment requirements for its employer-members must maintain a recruitment report containing the information required by 20 CFR 655.156 in a manner that allows the Department to see the recruitment results for each employer-member identified on the H-2A application and approved job order.

We received several comments on these issues. Mountain Plains, Western Range and the SBA Office of Advocacy commented that employers engaged in range herding and livestock production cannot find qualified and available U.S. workers to fill their positions despite employers' efforts. ASI indicated that the labor demographics changed in the 1980s and 1990s, after which time the industry has not been able to find U.S. workers who were interested or had a background in herding. Western Range stated that in 2012 only 22 U.S. workers applied for approximately 1,000 shepherd positions with its employer-members, and of those 22 applicants, only 2 were considered qualified and ultimately hired. However, Western Range reported that neither of the two U.S. workers hired completed the work contract period. Mountain Plains stated that, in 2014, its employer-members sought to hire workers for more than 1,000 range sheep and goat herding, range livestock production, sheep shearing, and wool grading positions. Of the two qualified U.S. workers who applied, one was not interested in the job and the other was hired but didn't complete the work contract. The Department also received a number of comments from other employers, professional associations, and private citizens generally noting the unavailability of U.S. workers. These comments noted that despite recruitment efforts, U.S. workers are not interested in range herding and production of livestock jobs, and that those who do express initial interest tend to not complete a season. One commenter indicated that U.S. workers are not willing to work more than 40 hours a week. A different commenter indicated that the shortage of both sheep shearers and shepherds is not just limited to the United States, but is worldwide. Another commenter indicated that the domestic labor force is drawn instead to higher paying job sectors, such as oil and gas, where jobs are prevalent in the West. Another employer noted low unemployment

rates in her State, and indicated that her business hires interns through a trade association, the Navajo Nation, and from local colleges, but that these workers are available only on an ad hoc basis, and do not provide a stable and consistent labor force. In addition, a number of commenters generally urged the Department to maintain the status quo and keep the existing special procedures for these occupations without change, expressing satisfaction with the existing program variances.

The Department also received a comment from a SWA employee commenting as a private citizen, stating that employers should be required to engage in maximum recruitment efforts and affirmatively request a referral report from the SWA. The commenter also asked the Department to address the commenter's perceived employer preference for foreign workers, the experience requirements in the job order, and the difficulty U.S. workers have to predict their availability a month or two in advance of the employer's start date. The commenter thus raised obligations applicable to all H-2A employers (including the prohibition against preferential treatment of foreign workers and the timing of recruitment in advance of the employer's start date of need). All employers seeking H-2A workers are required to conduct at least the recruitment activity the Department requires, and to cooperate with the SWA referring U.S. applicants. These obligations are not new or specific to these range employers. The commenter did not suggest specific additional recruitment activity or suggest that newspaper advertisements should be retained as a requirement. We note that we address acceptable experience requirements for these range occupations in Section IV.B.2.a. of this preamble.

None of the commenters disagreed with the Department's proposed position that newspaper advertisements are impractical and ineffective recruitment tools for these range occupations. Accordingly, the Final Rule adopts the proposal to expand the current variance to newspaper advertisements to all range occupations eligible for processing under this rule.

After considering all the comments received on this section, we have decided to retain the original § 655.225 as proposed. Because both range herding and livestock production cover multiple areas of intended employment in remote, inaccessible areas within one or more States, and where fewer communities have newspapers, the newspaper advertisement is impractical

and ineffective for recruiting domestic workers for these types of job opportunities. The CO will direct the SWAs to keep the job order on its active file until 50 percent of the period of the work contract has elapsed for all employer-members identified on the approved job order. The SWA will refer all qualified U.S. workers to the association, and the association has an obligation to make every effort to accommodate a U.S. worker's worksite location preference (e.g., the location with an opening nearest to his or her place of residence). In addition, this Final Rule clarifies that an association handling the recruitment requirements for its employer-members must maintain a recruitment report containing the information as required under the standard H-2A regulation, at 20 CFR 655.156, in a manner that allows the Department to see the recruitment results for each employer-member identified on the H-2A application and approved job order. As we have done above, we note again that this section of the Final Rule contains the only variances the Department is making from the general post-acceptance procedures in the standard H-2A regulations for eligible employers seeking workers in range herding and production of livestock occupations. Unless specifically addressed in these provisions, employers must comply with the post-acceptance procedures in 20 CFR 655.150-655.158.

E. Range Housing

1. Section 655.230 Range Housing⁵⁵

a. Background

The TEGLs require employers to provide free housing to H-2A and corresponding U.S. workers who are not reasonably able to return from their work location to their residence within the same day. Because of the transient nature of the work—going where the herd goes, often in remote areas at some distance from the employer's ranch or farm—the TEGLs recognize that permanent housing is not feasible. Instead, the TEGLs recognize the need for housing that could be moved from one area on the range to another. Under the practice permitted under the TEGLs, most workers were provided a mobile camper that would be towed from one location to another as housing. Tents and other shelters were also used for this purpose, typically where there was no practical alternative given limited

accessibility by vehicle because of remoteness and terrain.

In the NPRM, the Department proposed to include in this section the following basic requirements that were established under the TEGLs: (1) Employers subject to this rule may use mobile housing where more permanent housing is not practicable because of the remote and changing location of the employment or its terrain, or the worker is engaged in the production of livestock or activities minor, sporadic, and incidental to herding or production of livestock; (2) OSHA standards for range workers, if promulgated, must be followed; (3) the mobile housing must be inspected by state officials at least every three years, and, if certified as meeting established standards, annually by the employer until the next scheduled state inspection; (4) if a worker is working on or near the employer's ranch, farm, or other central facility (defined as within a reasonable distance for a worker to travel each night), the employer must provide the worker access to a toilet, kitchen, and a cleaning facilities for the worker and his or her clothing, including showers with hot and cold water under pressure; and (5) where a worker is residing temporarily at the employer's fixed-site housing, rather than using his/her mobile housing for this purpose, the fixed-site housing must meet the requirements of 20 CFR 655.122(d) (the housing standards generally applicable to H-2A employment).

The Department explained in the NPRM that since there are no specific OSHA standards for mobile housing on the range, employers were required to follow the requirements established by the TEGLs and that the Department proposed to include these requirements, with some modifications, in this section and section 655.235. The Department invited specific comment on whether an employer should be required to provide a range worker a sleeping facility in fixed-site housing when the worker is working at or nearby the employer's ranch, farm, or some other central location.

b. Comments and Discussion

A few commenters stated that a range worker's housing should meet the same or similar standards applicable to H-2A workers or other workers engaged in agriculture. Most commenters, however, recognized the unique nature of range employment and addressed various aspects of proposed section 655.230, including inspection of mobile housing, and access to kitchen, toilet, washing, and laundry facilities when a worker is at or nearby an employer's ranch or

farm. Worker advocates, employers, and their associations responded to the Department's invitation for comment on whether an employer should be required to provide sleeping accommodations (other than the worker's mobile camp) when a worker is performing work at or near an employer's ranch, farm, or some other central location. Additionally, a few commenters noted that the Department's proposal should be clarified to address temporary bunkhouse-type structures used in remote areas in Texas and Montana, and possibly other areas, to house workers when working in these areas. The comments on these particular issues and the Department's resolution are discussed immediately below by issue.

i. Inspection

Several employers and a State agency stated that the current inspection system is working and that there is no need to change the system. They explained that SWA inspection of mobile housing is occurring as often as once or twice a year in some places. One employer, Eph Jensen Livestock, however, noted the application of the standards by inspectors and investigators sometimes varies drastically, and asked the Department to better ensure clarity and consistency in inspections. In contrast, worker advocates asserted that the mobile units used by employers often failed to meet the existing standards. They stated that the Department should better monitor and track mobile housing by requiring annual inspections and instituting a system to track the units inspected, and create an ombudsman position to ensure compliance. They recommended the elimination of the self-inspection process, and stated that if the system was continued there should be more detailed requirements for the self-certification system. In their view, some employers require workers to use uninspected, unsafe units, sometimes in place of those that had been presented for inspection. The worker advocates stated, as a general rule, that the mobile housing is not adequately maintained, especially given the rigors of climate and terrain.

As stated in the preamble to the NPRM, mobile housing must comply with the established standards in order to provide a worker with adequate shelter in circumstances where the climate may be harsh and the terrain is often rough. Regular maintenance and inspection of the mobile units are necessary for a worker's wellbeing. In the Department's view, the proposed inspection system—properly applied—including the denial of certification

⁵⁵ The title to this section, which was "Mobile Housing" in the NPRM, has been changed to "Range Housing" in the Final Rule for the reasons discussed in this section of the preamble.

where a mobile unit is deficient and the assessment of an appropriate penalty for failing to maintain standards, provides sufficient remedies to protect workers. SWAs are encouraged to review their inspection procedures and to increase the frequency of inspections where they deem appropriate. As noted by some commenters, some states require at least annual inspections, and we encourage other states to do so. SWAs are encouraged to share best practices to improve inspection procedures, develop checklists to assist employers in conducting self-inspections, and take steps to prevent the alleged fraudulent practice in which some employers ignore the inspection process by providing uninspected mobile units to workers under the guise that they have been inspected.

ii. Providing Kitchen, Toilet, Shower, Laundry and Sleeping Facilities for Workers Performing Work at or Near a Ranch or Farm

No commenters directly opposed the Department's proposal regarding provision of kitchen, toilet, shower, and laundry facilities where a worker is performing work at or near an employer's ranch, farm, or other location where these facilities are already available to other workers. Some commenters stated that they routinely provide these services to the workers. The worker advocates did not oppose the idea that these services must be provided to workers, but, as discussed below, they favored requiring employers to provide fixed-site housing, meeting the usual standards for H-2A housing, for any range worker who was at or nearby a ranch or farm for more than one week.

In responding to the Department's inquiry whether employers should be required to provide living facilities separate from the mobile housing while the herder is working at or near the ranch, several employers and employer associations, including Mountain Plains and Western Range, Lava Lake Land and Livestock, and the Siddoway Sheep Company, voiced strong opposition to the idea. Many stated that such a requirement would be unreasonable because it would require them to construct a structure that would have to meet all the OSHA requirements for fixed-site housing, even though the structure would be used only a few weeks per year. They instead supported the Department's proposal to allow range workers to continue to live in their assigned mobile housing unit when located near a fixed-site ranch location. As mentioned above, however, worker advocates disagreed, asserting

that workers should be provided fixed-site housing that meets all the OSHA standards, whenever a worker is at or near the ranch or other location for more than a week. In their view, providing access to running water, toilets, and bathing facilities does not replace an employer's requirement to provide housing meeting the normal standards for H-2A workers.

The Department is adopting its proposal without change. We recognize that there are times when the mobile housing is located at or near the ranch or a central location for certain operations that are a normal part of the herding cycle, such as birthing, shearing, or branding. In such instances, the practice has been for workers to use mobile housing, even where access to fixed housing exists. Under the Final Rule, an employer may continue this practice so long as it provides the workers with access to the other facilities required by this section. However, the Department encourages employers to make appropriate housing available at the ranch, if they have it and if the workers prefer to stay in that housing.

iii. Remote, Stationary Range Housing

A few commenters, including Mountain Plains and Western Range, the Texas Sheep and Goat Raisers Association, and an employer, William Ashby Maltsberger, expressed concern about the use by employers of remote, but not mobile, housing in their range operations. The commenters stated that these operations, located in Montana and the southern plains states, use strategically located wooden bunkhouses in remote areas as they move herds through their grazing routes. The commenters stated that in light of this practice, it would be inaccurate for these employers to include a statement about "mobile housing" in the job order, as would be required under the Department's proposal. They expressed concerns, too, that unless the Department modified its proposal, these employers could be denied use of range workers under the H-2A program.

The Department's use of the term "mobile housing" in TEGLs and the NPRM was intended to distinguish remote housing provided to workers engaged in range work from fixed-site housing at a ranch or farm. The term's usage was not designed to preclude employers from using remote, but stationary, housing. Accordingly, the title to this section has been changed to "Range Housing," not "Mobile Housing," and the regulatory text for §§ 655.230 and 655.235 has been revised to clarify that such housing may be used

to house range workers under this rule while they work in remote areas so long as such housing meets all the requirements of this section and the minimum standards established under § 655.235.

2. Section 655.235 Range Housing Standards.⁵⁶

a. Background

The NPRM, in large measure, proposed to codify the minimum standards historically applied by the Department to mobile housing used by sheep, goat, and cattle herders while working on the range. These proposed standards, which closely track the requirements in both TEGLs, were generally consistent with the housing rules for temporary agricultural workers published under 20 CFR part 654, subpart E, as adapted to the unique circumstances of range workers. Providing suitable housing for workers on the range presents unique challenges, given the continuing movement of the range workers as they lead their herd to new grazing areas, often in remote locations at considerable distance from the herd's starting or interim locations, and the relatively small number of workers engaged in this work. In most instances, the housing, which is defined to include tents, moves along with the worker and the herd to the next grazing location. The housing standards, although providing general requirements regarding their physical structure and inspection (see also § 655.230), also specify requirements relating to the provision of facilities (e.g., for sleeping, heating, and cooking) and services (e.g. water supply and refuse disposal). These standards are often flexible; a particular standard typically allows an employer to select from various options and to make adjustments for particular location, terrain, and other circumstances. The standards necessarily differ, sometimes significantly, from the requirements for less temporary, fixed-site housing used by other workers engaged in agricultural duties. Thus, while the Department has standard H-2A regulations governing fixed-site housing for other temporary workers engaged in agriculture, these regulations cannot be readily applied to the range.

The term "mobile housing" suggests a structure capable of being transported from one location to another. The housing provided to herders most often

⁵⁶The title to this section, which was "Mobile Housing Standards" in the NPRM, has been changed to "Range Housing Standards" in the Final Rule for the reasons discussed in the prior section of the preamble.

is a wheeled-structure, varying from recreational type-vehicles seen every day on highways, to other vehicles, more rustic in appearance (“campers”), trailed behind cars or trucks. The proposed rule, like the TEGs, established requirements for these vehicles, but it also included requirements, as did the TEGs, applicable to tents, which may be used in limited circumstances to house herders working on the range. These standards were not intended to prohibit the use of other structures used to temporarily house workers on the range simply because they were not moved or could not be moved. Provided a structure satisfied the “mobile housing” standards, the fact that it was not moved would not exclude its use. In the Final Rule, this point is made explicitly, in order to resolve concerns about the use of remote fixed structures in some areas of the country, situated along grazing trails, to temporarily house the herders.

The Department proposed to continue the requirement under both TEGs that each worker must have his or her own comfortable bed, cot, or bunk, along with a mattress, to sleep. As noted in the NPRM, however, the Department recognizes that where the housing is a one-person unit, occasionally range work requires that two workers must share or use the same bed, because terrain, remote location, or demands of the herd, prevent the employer from bringing a separate housing unit to the site, and the camper is a one-person unit. These situations are intended to be rare and the Department proposed to continue to restrict an employer from requiring workers to share a bed for more than three consecutive days. The Department proposed to continue the requirement that the employer must provide each worker with a separate sleeping bag or other bedding when sharing a bed temporarily.

b. Comments and Discussion

i. General

Worker advocates asserted that the proposed minimum standards too closely mirror the existing housing requirements, which they criticized as outdated, too general, and inadequate to meet the workers’ basic needs for shelter, sleeping, cooking, cleaning, and personal hygiene. Worker advocates urged the Department: To forbid the use of kerosene lanterns and other items using combustible fuel; to require newer, safer heating, lighting, cooking and refrigeration facilities, including solar-powered items, LED lights, and battery packs; to require emergency, hand-cranked generators; to require

portable camp toilets, and in areas such as corrals, where several individuals may be working, outhouses; and, on at least a monthly basis, to provide each worker the opportunity to take a hot shower and use a washing machine.

The worker advocates took particular issue with the proposed heating standard. Under the NPMR’s standard, an employer was not required to provide heating unless the outside temperature remains below 50 degrees for 24 hours. They stated that this standard ignores the wide temperature fluctuations in some locations on the range and exposes range workers to altitude- and cold-related medical conditions, such as frostbite, chilblains, and trench foot. They asserted that the Department should establish a requirement that an employer must equip each housing unit with a heater that can maintain at least a minimum prescribed temperature inside the unit, advocating for heaters capable of keeping the temperature at or above 68 degrees.

In their comments, the worker advocates included a thumbnail sketch of their view of the herders’ working and living conditions on the range:

[Herders part] of the year work and live on the valley floor. During the rest of the year they tend sheep in the mountains and deserts. Living alone, they have no contact with other humans for days or weeks. They live in small, dilapidated, one room trailers, called sheep camps, or tents. Most trailers have no form of heating or air conditioning. They become unbearably hot in the summer and intolerably cold during the winter. There are no bathing facilities. There’s no running water. No field toilets are provided.

Acknowledging that the workers traverse many different locations in performing their sometime strenuous herding duties, often in remote and rugged areas that require the use of mobile housing, including tents, the employers paint a different picture than the worker advocates. From the employer’s perspective, the nature of range work, especially in areas where terrain is mountainous or otherwise not easily accessible, limits their ability to provide housing that exceeds the existing standards. Work is often performed on land managed by federal agencies, including the BLM and the Forest Service, which forbid more permanent housing and regulate such things as waste removal and food storage. At the same time, the employers indicated that where the location of the herders’ work permits, workers enjoy conditions better than required by the standards, that the mobile housing meets established certification requirements, and that the herders find

their housing suitable and appropriate for their line of work. The employers stated that the workers are resupplied on a regular basis, prefer their mobile housing to alternative structures, and are treated no less well than other employees whose work is essential to an employer’s business success. As stated by the Texas Sheep and Goat Association: “The ranchers treat the herders . . . in many cases, as family.” A similar sentiment was expressed by the I & M Sheep Company: “[The H–2A workers] have worked very hard for our family and have become more than just employees to us,” adding that “[w]ithout these individuals, our sheep operation would cease to exist.” To the extent there are problems with compliance, the employers stated that better enforcement, rather than more stringent standards, is the approach that should be taken.

No commenter directly stated that the existing standards, established under the TEGs, were too stringent; however, as will be discussed, some comments demonstrated that some employers appeared uncertain about some of these requirements. In general, several employers and their associations suggested that the existing standards are just about right, protecting workers’ health and safety without imposing excessive or unnecessary costs on employers. As stated by an employer, Theresa Dalling: “The special procedures . . . have worked for [our industry] over the past 35 years. There is no reason to change what has worked.”

Although the worker advocates and employer commenters disagree about the degree to which employers comply with the existing requirements, they agree that some employers fail to comply with the requirements and that compliance can and should be improved. The Department agrees. Compliance can be achieved not only through better enforcement but also through outreach efforts to educate employers and workers about the applicable requirements. In the Department’s view, this rulemaking has brought focus to the difficult circumstances under which herders work, the unique features of their employment, and the difficulties confronted by them and their employers, as they perform their work, conduct their business, and attempt to earn a just wage and profit.

Although we conclude that the existing standards, overall, adequately protect the health and safety of the herders, some adjustments and clarifications to the standards are appropriate. These adjustments can be

made without imposing any unreasonable or unnecessary costs or burdens on employers. In its proposal and the Final Rule, the Department has sought to help employers understand and comply with their housing-related obligations, without sacrificing simplicity and flexibility, and to better inform workers and their advocates about the workers' housing-related rights. The comments received on housing-related issues have been informative and have helped the Department to shape the Final Rule, revising the proposed regulatory text, as needed, to address particular concerns raised by commenters. Each change is discussed below with regard to each standard as set forth in the individual paragraphs of § 655.235.

ii. Particular Standards

(1) Change to Title and Opening Paragraph

Both TEGLs and the NPRM stated generally that an employer may satisfy its housing obligations by providing workers use of a mobile unit, camper, or similar mobile vehicle that meets the prescribed standards. The NPRM proposed "Mobile Housing" as this section's title. As discussed in Sec. IV.E.1. of the preamble in connection with § 655.210, the term "mobile housing" fails to include remote fixed-site structures that have been used in Texas, Montana, and other areas to temporarily house range workers. These bunkhouse-type structures are not mobile, but are placed at strategic locations on grazing trails to provide housing for workers as they proceed with a herd along the trail. In the Final Rule, we have revised the title to read "Standards for Range Housing" and made plain that any structure used to temporarily house workers on the range must meet the standards prescribed by §§ 655.230 and 655.235. Further, as discussed below, the Department received several comments that suggest confusion about the use of tents to house workers on the range and how the particular requirements set forth in §§ 655.230 and 655.235 apply to tents. For added clarity, we have revised the regulatory text to specify that tents are structures covered by these sections.

(2) Paragraph (a)—Housing Site

Both TEGLs and the NPRM provide that a housing site must be well drained and without depressions that would allow stagnant water to collect. No comments were received on this point and the Final Rule adopts the proposal without change.

(3) Paragraph (b)—Water Supply

(a) Background

Both TEGLs require employers to provide workers an adequate and convenient supply of water that meets standards established by the State health authority. The TEGLs require that the employer provide an amount sufficient for the normal drinking, cooking, and bathing needs of each worker. The TEGLs also require an employer to provide an adequate supply of potable water, or water that can be easily rendered potable, and to provide individual drinking cups to each worker. In the NPRM, the Department included these requirements. It clarified that the supply of water must be enough for the worker's normal cooking, consumption, cleaning, and laundry needs. Under the proposal, the employer was required to provide the worker with the means to make the water potable. This section overlaps with section 655.210(c), which requires an employer to specify in the job order that it will provide potable water or "water that can be easily rendered potable and the means to do so."

The preamble to the NPRM explained: "Potable water is water that meets the water quality standards for drinking purposes of either the state or local authority having jurisdiction over supplies of drinking water or the U.S. Environmental Protection Agency's National Primary Drinking Water regulations, 40 CFR part 141." 80 FR at 20313. The Department explained that this definition mirrors the OSHA field sanitation regulations that define potable water for agricultural establishments, 29 CFR 1928.110. *Id.* It further explained that the supply of readily available, potable water is necessary to ensure that water is available for cooking and consumption by the worker, and that OSHA requires that drinking water always be available in amounts needed to satisfy thirst, cooling, waste elimination, and metabolism. As proposed by the Department:

An adequate and convenient supply of water that meets the standards of the state or local health authority must be provided. Water used for drinking and cooking must be potable or easily rendered potable, and the employer must provide the worker with the means to make the water potable. The amount of water provided must be enough for normal cooking, consumption, cleaning, laundry and bathing needs of each worker; . . . and [i]ndividual drinking cups must be provided.

80 FR at 20342.

The Department specifically invited comment on (1) how much of the water

should be potable (or easily rendered potable) for cooking and consumption; (2) how much water is sufficient for cleaning, laundry, and bathing requirements; (3) what alternative water supplies may be used when exigent circumstances preclude the employer from transporting water to the worker; and (4) what means are available to make alternate water sources potable for cooking and consumption. 80 FR at 20313.

As discussed further below, we received many comments on whether it was necessary to establish a standard other than to simply require that an employer provide an "[a]dequate and convenient supply of water that meets the standards of the state health authority . . . [in an] amount . . . enough for normal drinking, cooking, and bathing needs of each worker," as required under the TEGLs. In the Final Rule, the Department, as proposed in the NPRM, specifically requires that the water used for drinking and cooking must be potable or easily rendered potable with the means to make it potable, consistent with the TEGL requirement referring to the State health authority standards.

The Department only received a few comments, discussed below, on the amount of potable water needed for consumption and cooking. The Final Rule requires that employers on a regular basis must supply, *i.e.*, transport to the workers' housing locations, enough water to ensure that each worker has at least 4.5 gallons of potable water available for the worker's use, per day, until resupplied. The Final Rule provides a limited exception for situations where terrain prevents the delivery of supplies by motorized vehicle. In those circumstances, an employer must identify alternative sources of water, such as springs, streams, or snow, that may be used by workers, and provide the workers the means to test and, by filtering, chemical purification or other methods, to easily render the water potable.

The Department only received a few comments on the amount of non-potable water required to meet the cleaning, laundry, and bathing needs of workers, which are discussed below. The NPRM did not specify an amount of water needed for these purposes, nor preclude an employer in exigent circumstances from requiring that workers rely on alternate sources of water, where available, for these purposes. The Final Rule adopts the approach taken in the proposal.

The Department received several comments on what would constitute an exigent circumstance that would permit

an employer to require workers to rely on alternative sources of water, set out below. Worker advocates urged the Department to limit the exception to emergencies, such as where a forest fire prevented the delivery of potable water. Employers and their associations urged the Department to provide a broader exception, many asserting that they should not be required to transport any water to any housing locations where alternate sources of water are available. In the Final Rule, the Department takes a middle course, allowing an employer to use the exception where housing is located in areas that are not accessible by motorized vehicle. As discussed below, there will be emergency situations where an employer may encounter some delay in providing supplies. We have decided that it is better to address those situations on a case-by-case basis, rather than by attempting to define their scope. In our view, it is difficult to anticipate the particular situations that might arise. Stating that such an exception is available, without precisely defining its scope, could be used by some employers to circumvent their obligation to supply enough water to meet the range workers' needs.

The Department received several comments, which we address below, on the means by which water for drinking and cooking may be rendered potable. The Final Rule does not require that any particular method or device must be used for these purposes. The Final Rule, like the proposal, simply requires that the employer—in those limited circumstances where it is not required to transport potable water for these purposes to a range worker—must provide the means by which the worker may easily render the water potable and clarifies that the employer must provide a worker with the means to test the physical, chemical, and bacteria content of the alternate water sources available so that the worker is able to determine whether it is necessary to treat the water and the most suitable means of making the water potable.

The Department received no comments on its proposal to continue the requirement that an employer must provide individual drinking cups to each worker, and the Department, without further discussion, is including this requirement in the Final Rule.

(b) Comments

The worker advocates generally supported the Department's proposal, but suggested that the Department should require employers to provide potable and non-potable water in amounts, prescribed by the Department

to meet the workers' minimum daily needs. They stated that employers should be required to deliver this water to the worker and should not be permitted to require a worker to rely on alternative sources of water to meet any of the worker's needs. They asserted that the use of alternate sources of water should be strictly limited to emergency situations such as forest fires or other disasters that temporarily prevent employers from reaching the workers.

Although the employers and their associations generally supported the proposed standard, they strongly opposed any limitation on their use of natural sources of water to satisfy this obligation. They acknowledged that workers should always have enough water for drinking, cooking, bathing, and laundry, but were offended by the suggestion that any legitimate employer would ignore this obligation. They expressed a fear that the Department would "over-regulate" and, in doing so, would significantly impair their ability to successfully operate their businesses.

Mountain Plains and Western Range stated that employers regularly supply their herders with water for drinking, cooking, and bathing unless the herders are working in remote locations that have natural sources of water. Several employers and two state agencies (New Mexico and Utah) explained that workers' needs and the means of providing water vary depending on the season, location, and particular herding operations. Two employers, Henry Etcheverry and Siddoway Sheep Company, described the particular difficulties involved in transporting heavy materials, including water, to herders working in high mountain areas where access is only by horse. Siddoway Sheep Company estimated that it would need an additional eight pack horses per herd to supply workers if natural sources of water could not be used for these purposes.

Mountain Plains and Western Range and two employers, Cindy Siddoway and Henry Etcheverry, explained that there has been no history of workers becoming sick from using natural water sources. Another employer, Sharon O'Toole, noted that range workers are careful with water because it is often not potable in their native countries.

The comments included a variety of cost-effective methods and devices that they stated could be used to make natural sources of water potable, including boiling water, straining melted snow through coffee filters, iodine tablets, ultraviolet purification, bottles, osmosis filters, water purification bottles, and germicidal tablets. One employer, the Siddoway

Sheep Company, recommended the use of hand-held bottles designed for water purification, because, its experience has been that workers will risk drinking water without testing or treatment if the only method available leaves an unpleasant taste in the water.

The Department received only a few comments in response to its request for input about the minimum amount of water that should be provided to workers on a daily or weekly basis. Relying on a statement prepared by an expert on the nutritional requirements of rural populations and immigrant workers, the worker advocates asserted that at least 32 gallons of potable water was needed weekly for each worker, for consumption and dishwashing, a daily average of a little more than 4.5 gallons. The only employer to comment directly on this point, Sharon O'Toole, estimated that workers need about 40 gallons per week (5.7 gallons per day) for these purposes. The worker advocates recommended that the employers be required to provide an additional 50 gallons of water (non-potable) for cleaning, bathing and laundry.

The worker advocates submitted short statements from three herders, one of whom stated that about 35 gallons would be the minimum amount of potable water required for each range worker per week (5 gallons per day). One herder stated that his employer had only provided him with a total of 40 gallons of per week (suggesting this amount was intended for the all the worker's drinking, cooking, dishwashing, bathing, and laundry needs). He explained that sometimes he would run out of water before he was resupplied, forcing him to ask other herders, if any were nearby, for water, and that for bathing he had to get water from the sheep's water tank or ponds. Two of the herders said that they were forced to continue wearing dirty clothes if they were not located close to a natural water source.

Worker advocates requested the Department to clarify that separate water supplies should be provided to workers, apart from any supplied for the use of dogs or horses. One commenter, Sims Sheep Co LLC, noted that potable water should be stored in a container appropriate for that purpose. This employer also noted the difficulty of keeping water from freezing, recommending that employers be required to provide containers small enough to be kept inside the worker's housing to prevent the water from freezing.

Mountain States and Western Range requested that the Department not require employers to provide water for

clothes washing, if an employer offers laundry services and the worker expresses no preference to do the laundry on his own. Two employers, Carl and Katy Day and Warren Roberts, stated that they regularly pick up the workers' dirty clothes and return the clothes after washing, often weekly, when they resupply the camp. A Utah state agency stated that requiring employers to provide water for laundering places an unnecessary burden on employers.

(c) Discussion

After reviewing and considering all the comments on this provision, we first determined that workers' health and safety are unnecessarily put at risk by requiring an employee, on his or her own, to secure water for essential needs. While working on the range, a worker is always there at the convenience of the employer; thus, it is our view that, at the most fundamental level, it is the responsibility of the employer to ensure the worker's safety while he or she is serving the employer's business interests. The provision of water, no less so than providing a shelter to sleep in, or food to eat, is properly an employer's responsibility where the worker's "residence" is the range, and all his paid and unpaid time there is spent serving the employer's interests. We acknowledge that most employers are responsible and, as such, try to ensure their worker's safety, and that most employers regularly, even in difficult circumstances, extend their best efforts to keep their workers safe. Unfortunately, some employers are not so responsible, and the Department must keep this in mind in setting standards for a workplace, whether it is a factory or the range. Our determination that an employer must provide workers with necessary potable water—the only alternative to leaving the worker to obtain it on his or her own—rests on the need to regulate the actions of noncompliant employers, as well as because the alternative leaves the range workers at too much risk. They work in a place where weather conditions may be severe, temperatures are extreme, drought or near drought conditions may exist, and they are often at considerable distance from their employers and without any ready alternative if their water runs dry.

We next determined that setting a recommended minimum amount of water to satisfy an employer's obligation would benefit both workers and employers. Setting a minimum amount should prompt immediate action by an employer whose practice has been to provide significantly less than this

amount, thereby endangering, knowingly or not, the health and safety of its workers. In reviewing the comments, it became clear that many employers, especially in some locations and during certain seasons, have relied on natural sources of water primarily, if not exclusively, to meet or attempt to meet the workers' needs. Thus, having determined that it should be the employer's responsibility to provide the water, not one to be borne by the worker, there was a need, in our view, to establish a ready benchmark to enable these employers to estimate the amount of water they will now have to provide workers, information that it would need to know in order to establish a plan for transporting this water to their workers.

The comments submitted by the worker advocates helped inform the Department about setting the standard at an appropriate amount. Our consideration was guided by a statement included in the worker advocates' comment on this point. The statement was prepared by Sarah A. Quandt, Ph.D., a member of Wake Forest University's Department of Epidemiology and Prevention. She is a recognized expert on issues relating to food and nutrition among rural populations. She has conducted research involving immigrant workers, including crop and construction workers.⁵⁷ Based on her experience and considering research published by the U.S. Departments of the Army and Air Force, she estimated that workers would require about 2.5 to 3 gallons of water per day for consumption to which she added .5 gallon per day for cooking and 1 gallon per day for washing dishes.

The employer's estimate, too, was helpful. Although its recommended weekly amount was about 8 gallons higher (by about one gallon a day) than Dr. Quandt's estimate, the two were close enough to suggest there might be a shared understanding among stakeholders about the amount of water required to meet the essential needs of an individual engaged in range work. In further considering the issue, the Department consulted two reference guides: The U.S. Army Water Planning Guide, 2008 (Army Water Guide)⁵⁸ and the Water Guide for Emergency Situations, prepared by the U.N. High Commissioner for Refugees (U.N. Water

Guide).⁵⁹ The Army Water Guide provides various standards for estimating the per capita water need for troops, depending upon the particular operations in which the troops are engaged. The estimates vary by climate: hot-tropical, hot-arid, temperate, and cold. The Army Water Guide also provides an overall, per capita estimate for sustained operations, again setting standards by climate. We focused on the estimates for hot-arid, temperate, and cold climates. Herding in the United States primarily occurs under those conditions. For drinking and food preparation, the various estimates follow: 5.23 gallons for hot-arid conditions; 3.58 gallons for temperate conditions, and 4.13 gallons for cold conditions. Water Guide, Chart of Standard Planning Factors, at II-A-2. The U.N. Water Guide recommended a daily allocation of 15 liters (nearly 4 gallons). Finally, we considered the water standards prescribed by the State of California for various industries, including agriculture.⁶⁰

Based upon our review of the comments and the authoritative sources noted, we conclude that 4.5 gallons is reasonable as a recommended daily minimum amount of potable water that an employer should provide for each range worker for drinking and cooking. In setting this amount, we have balanced the need to provide workers a sufficient amount of potable water to meet their essential needs and the practical ability of employers to supply the appropriate amount of water without undue burden. Setting the minimum recommended standard at 4.5 gallons per day for drinking and cooking, rather than at the employer's higher estimated level, frees space on an employer's trailer or truck to transport supplies and other items to locations that may be distant from the employer's ranch or farm. Further, we conclude that a more conservative estimate is reasonable for setting this standard. It reduces the initial burden on employers, while providing greater protection to workers than is provided by the existing standard, which does not specify a recommended minimum amount. Some of the employers under this standard

⁵⁹ The U.N. Water Guide is available at <http://helid.digicollection.org/en/d/junr01/5.html>.

⁶⁰ See State of California, Department of Industrial Relations, Guidance for Employers and Employees on the New Requirements of the Heat Illness Prevention Regulation Amendments, California Code of Regulations, Title 8, Section 3395 (discussing changes, effective May 1, 2015, concerning employer requirements relating to work performed under hot conditions and continuing the State's requirement that covered employers must make available 2 gallons of drinking, per worker, for each 8-hour shift).

⁵⁷ A list of Dr. Quandt's publications may be located at <http://www.ncbi.nlm.nih.gov/pubmed?cmd=PureSearch&term=Quandt%20SA%5BAuthor%5D>.

⁵⁸ The Army Water Guide is available at [http://www.quartermaster.army.mil/pwd/publications/water/Water_Planning_Guide_rev_103008_dtd_Nov_08_\(5-09\).pdf](http://www.quartermaster.army.mil/pwd/publications/water/Water_Planning_Guide_rev_103008_dtd_Nov_08_(5-09).pdf).

will be delivering—for the first time—a large supply of potable water to their workers who previously relied upon natural sources of water as their sole or primary source of water for drinking and cooking. The employer may take into account the worker's current supply of potable water when replenishing the water. For example, if an employer resupplies workers on a weekly basis and the worker has consumed only 25 gallons of a week's supply of 31.5 gallons, the employer may choose to provide only 25 additional gallons of water until its next resupply.

Thus, to meet its obligations, an employer must deliver potable water on a regular basis so that its workers will have the requisite daily amount available during the supply and resupply cycle (except in exigent circumstances where alternative sources may be used to satisfy this requirement). It deserves emphasis that, even if the employer provides the daily recommended minimum amount of potable water, it remains its overriding duty to provide an adequate amount for each worker, based on the needs of a particular worker. This need will vary from individual to individual, and the appropriate amount is affected by many factors, including temperature, humidity, wind, the availability of shade, an individual's weight, and the length and intensity of physical activity. In other words, particularly in a dry or hot climate, employers may well be required to provide more than the 4.5 gallon general minimum.

We have determined not to set a minimum amount of non-potable water that an employer must supply for bathing, washing clothes, or other uses. We have less confidence in estimating an amount for these additional purposes, given that bathing, showering, and laundering practices may vary considerably because they involve matters of personal choice that are affected by the availability of particular facilities. These purposes may require significantly more water than needed for consumption and food preparation and cleanup. Based on day-to-day experience, obtained in providing water for their workers, employers should be able to readily estimate the amount of water actually needed by workers for all their needs, and, where natural water sources are not available, they should be able within a relatively short time to estimate the additional amount of water they will need to provide their workers for bathing and washing their clothes. This approach addresses the concern that if water for laundry is not needed, the employer need not provide water for

this purpose. Moreover, this approach allows employers to rely on the worker's use of alternate sources of water for cleaning, bathing and laundry, where such sources are readily available.

The text of the rule also addresses other concerns raised by the commenters, including a clarification that this standard establishes a supply of water strictly for the worker's own use, not a source that may be used to provide water for dog, horses, or the herd. We have also retained and clarified the limited exception under which an employer, for exigent circumstances, may require workers to rely on alternate water sources to provide potable workers to employees. We have been persuaded that requiring potable water to be carried on pack horse would impose an unreasonable burden on employers. The regulatory text has been clarified so that an employer will qualify for this exception only where terrain would prevent delivery of water by motorized vehicle and the employer satisfies the additional conditions described below. In our view, the worker advocates' suggestion that exigent circumstances be limited to emergency situations, such as a forest fire, that would prevent the delivery of supplies to workers, is too restrictive and would impose an unreasonable burden on employers.

We have concluded that the interests of range workers and employers are better served by not providing for a broader exception for exigent circumstances. There will be some occasions, such as a fire or a severe storm, which may temporarily prevent an employer from providing supplies. In those instances, an employer will not be held noncompliant so long as it has been prudent in preparing for such a possibility, such as by providing a reserve supply of water for emergencies, having developed a plan for the extrication of their employees in such circumstances, and having available contact information for government and private agencies that are able to provide rescue services.

As pointed out by commenters, winter conditions may present particular difficulties because freezing temperatures may prevent the easy and immediate consumption of water. Therefore, we have revised the text of the rule to require that wherever and whenever the temperature can reasonably be expected to drop below freezing, the employer must provide containers, appropriate for potable water, that are small enough to be stored in the range housing to prevent freezing.

Regarding the requirement that employers must provide water sufficient

for bathing and cleaning, we are clarifying that this water must be clean and free from anything harmful that could be absorbed by the skin or clothing, but the water provided does not need to be potable or easily-rendered potable. For these purposes, an employer may always rely on natural sources of water (springs, streams, fresh snow), when these sources available at the location of the worker's housing. Where the alternate water source is the same source that will be used to water the herd, the herder's dogs and horses, or may collect runoff from areas in which herd excretes, the employer must undertake special precautions to protect the worker's health from risk.

As discussed above, the Final Rule permits an employer, in limited circumstances, to completely rely on natural sources of water to meet the worker's needs, including drinking and cooking. The Final Rule establishes the following conditions to rely on natural sources of water for worker consumption:

- The terrain or weather conditions of the area in which the worker's housing is located prevents the delivery of potable water by a motorized vehicle.
- The employer has identified natural sources of water that are potable or may be easily rendered potable in the area in which the housing will be located and these sources will remain available during the period the worker will be at that location.
- The employer provides the worker with the means to test whether the water is potable and, if not potable, the means to filter out contaminants and treat the water to render it potable.
- The employer must provide this information when it files its *H-2A Application for Temporary Employment Certification*.

In the Department's view, these conditions carry special importance given the presence of drought and near-drought conditions in parts of the United States, particularly in the Southwest, as well as the significant health risks posed if water sources become contaminated with harmful pathogens because of the presence of nearby herds.

Where the employer seeks to use this exception, it must provide the worker with a device that can test the physical, chemical, and bacteria content of the water and the means to render the water potable. Employers may choose from various approved methods and devices to satisfy this requirement. Potential choices for means to render water potable would include, among others, water purification tablets, portable water purification systems, water

purification bottles, and filtering systems. Whatever method or device is selected to test and make water potable, the employer must ensure that the worker is adequately trained in the proper use of the method or device, so that when necessary, the method or device is used correctly.

(4) Paragraph (c)—Excreta and Liquid Waste Disposal

Both TEGLs and the NPRM require that facilities must be provided and maintained for effective disposal of excreta and liquid waste in compliance with state or Federal requirements. Where disposal pits are permitted, the TEGLs and the NPRM state that the pits must be “fly-tight” and maintained in compliance with State and local sanitation requirements.

A few commenters expressed concern about the facilities employers provide to range workers for the disposal of excreta and liquid waste. A few commenters, including worker advocates, stated that employers should be required to provide camp-type portable toilets or outhouses for workers to use on the range. Another commenter stated that employers do not always provide a shovel with which to bury such waste. We have revised the regulation to address this concern.

The rulemaking record does not reflect what particular toilet facilities, if any, are provided workers. The Department would expect that an employer would choose to provide a portable, camp-like toilet for use by its workers. A strictly functional device, shielded from view if the herder is working with others, would appear to be relatively inexpensive and compatible with any State or Federal requirements concerning the disposal of excreta and liquid waste. The Department, however, is less convinced about the suggestion that employers should be required to provide an outhouse, which the Department interprets to mean a permanent or semi-permanent structure constructed of wood or similar material. Obviously, it would be impractical unless workers routinely used the same location to establish a “camp,” and even in these situations, it would entail construction and maintenance costs and would increase, perhaps substantially, an employer’s disposal costs. The Department assumes that similar costs would be entailed in the rental, purchase, use, and transportation of a construction-type “porta-john.” Further, the construction of an outhouse would likely be subject to land use restrictions on many parcels of land used for grazing, including Federal lands. Given the absence of information about current

employer practices in this area and uncertainty about legal and cost considerations, the Department declines the suggestion to revise the standard to require camp toilets or more substantial structures of this nature, notwithstanding the benefit they would provide for workers.

(5) Paragraph (d)—Housing Structure

Both TEGLs and the NPRM required that employers provide structures that are structurally sound, in sanitary condition, and in good repair to protect workers from the elements. Beyond this general duty, the TEGLs also specified a few particular requirements regarding the structure of the housing. The general and particular requirements were included in the NPRM.

Earlier, in the Sec. IV.E.1. of the preamble related to § 655.230, and throughout this section, we discussed various general comments and comments specific to particular requirements. Many of these bear on the structural suitability of a housing unit, but the Department received no comments specifically directed to this subsection and therefore the Final Rule adopts the proposal on this point without change, except to clarify that the requirements relating to housing, including the standard for structure, also apply to tents, except as discussed below.

Some employer comments suggested that there may be some confusion about the application of standards to tents. The proposal did not modify an employer’s obligations under the TEGLs to generally apply the same requirements to tents as apply to other range housing. The TEGLs and the NPRM require that an employer may use a tent to house workers only if the terrain or land use regulations prevent the use of more substantial housing and the tent is appropriate for the weather conditions. Further, where tents are used, they are subject to the same requirements that apply to campers or other structures, unless the standards provide otherwise. If it is feasible to provide electricity and mechanical refrigeration at a location, an employer must do so, even if the worker is housed in a tent. While such opportunities will be limited, the obligation remains. If the use of the tent is required by land use restrictions prohibiting more permanent structures, but electric service is available, the employer must provide it. See § 655.235(f). The TEGLs and the NPRM, however, specifically exempted tents from the requirements applicable to other structures—that they have rigid flooring and a second means of egress for escape (unless the tent is large and

has rigid walls), see § 655.235(e)(5). Further, the TEGLs and the NPRM prohibited the use of heaters in tents unless the heater was approved for such use and the tent is fireproof. The Final Rule contains these same requirements and exceptions.

(6) Paragraph (e)—Heating

Both TEGLs and the NPRM required that stoves or heaters using combustible fuels be safely vented and be shielded by fireproof material. They required that if a heater has automatic controls, it must be of the type that interrupts the fuel supply when the flame fails or a predetermined safe temperature is exceeded.

Neither the TEGLs nor the NPRM, however, required that each housing unit be equipped with a heater or a heating system, nor did either require the employer to ensure that the temperature inside the housing could be maintained at or above a certain level. The NPRM continued the existing standard under which employers could choose not to provide heated units. Under that standard, no heating is required for housing located in mild-climate areas unless the temperature is reasonably expected to drop below 50 degrees and remain continuously below that temperature for 24 hours. To maintain worker safety, however, employers that choose not to provide heating were required to provide the workers with proper protective clothing and bedding.

The worker advocates contended that the Department’s proposal ignored the wide temperature fluctuations in some locations where range workers are employed, and that the proposal would continue to expose range workers to altitude- and cold-related conditions that could lead to injury and illness. They asserted that the Department should instead require an employer to provide heating whenever the temperature inside the housing facility falls below a prescribed temperature, advocating in favor of setting this temperature at 68 degrees. The worker advocates also requested the Department to require that any devices that use combustible fuels (which would include those for lighting, heating, and cooking) should have fuel sources stored outside the housing structure. They further requested that the Department require that heating devices should be inspected annually by fire departments or heating specialists. No comments were submitted by employers or their associations on this point. However, as noted throughout this section of the preamble, employers and their associations generally opposed

any requirements that would go beyond those required by the TEGs.

The worker advocates have presented a persuasive argument that the Department's proposed heating standard does not adequately protect the health and safety of the workers. It is widely known that the hourly temperatures in the mountainous and desert areas in which herding is common can dramatically fluctuate over the course of a day. Even in areas where temperature changes over the course of a day generally fluctuate within a narrower range—areas that could be fairly described as mild and whose usual daily temperature reaches 50 degrees or higher—it is not uncommon for the temperature to drop below freezing or to feel as if it has when the weather is windy, rainy, or both. In these circumstances, a range worker should be able to obtain a heated shelter from the elements. Accordingly, the Final Rule revises the threshold at which heating must be provided. As revised, an employer must provide heating for a housing unit if the low temperature for any day in the work contract period is reasonably expected to drop below 50 degrees. If the low temperature for any day in which the housing unit is being used is not reasonably expected to drop below 50 degrees Fahrenheit, no separate heating equipment is required as long as proper protective clothing and bedding are made available, free of charge or deposit charge, to the workers.

The Department recognizes that this may require some employers—for the first time—to equip their range housing with heaters. The existing standard is simply inadequate to protect the health and safety of the range workers. The extra clothing and bedding is a poor substitute for a heater on a day when the temperature may remain below 50 degrees.

The Department is unpersuaded by the argument that it should require employers to provide housing units that will maintain a specified inside temperature. The Department has no present information that would allow it to set such a standard, particularly given the wide variety in the design of the housing units used by range workers and the uncertainty that a particular temperature could be achieved without undue expense to employers.

The Department is not convinced that it is necessary to add either a requirement that heating or heating system be inspected annually by a fire department or heating specialist, or a requirement that an employer can only provide a device in which the fuel source is stored outside the housing unit, particularly because the type of

device and fuel storage must fit the variety of current and future housing structures. The Final Rule retains the existing requirement under the TEGs that the units in which workers sleep must be constructed and maintained according to applicable state and local fire and safety laws. Moreover, the housing unit, including any heating equipment, would have to meet whatever inspection requirements are established by the SWA. In our view, this standard adequately ensures the safety of the workers. Accordingly, except for revising the proposed standard to limit the ability of an employer to provide an unheated housing unit, the Final Rule adopts the standard as proposed. Finally, as discussed above in Section IV.B.2.c., heating equipment and, where permitted, protective clothing and bedding, must be listed in the job order along with other required tools, supplies and equipment that will be provided free of charge or deposit charge.

(7) Paragraph (f)—Lighting

Both TEGs and the NPRM require that electrical service must be provided if feasible. Both TEGs and the NPRM required that where electric service is not provided, the employer must provide at least one lantern for each worker. Kerosene lamps were permitted.

The worker advocates, as previously noted, have broadly criticized the Department for not incorporating modern technology in its range housing standards. They have objected to the permitted use of kerosene lamps in the range housing, asserting instead that the Department should require battery or solar-powered devices. Although some employers mentioned that they provided solar power sources for some purposes, none indicated whether they were used to supply power for lighting. As noted throughout this section of the preamble, employers and their associations generally opposed any requirements that would go beyond those required by the TEGs.

In the Department's view, it is unnecessary and inappropriate to mandate, or categorically forbid, the use of any particular device. Kerosene lanterns have long been used by campers and other outdoors enthusiasts to provide lighting in temporary structures similar to range housing. On the present record, there is nothing that would justify the Department from banning their use. As discussed previously, employers are required to construct and maintain units that comply with applicable state and local fire and safety laws. Where such laws forbid the use of particular kinds of

lanterns or impose conditions on their use, an employer would be obliged to follow those laws. Moreover, it is in employers' interest to provide safe lighting options.

There were no comments received on the requirement that an employer must provide at least one lantern for each worker. The Final Rule adopts the proposed lighting standard without change.

(8) Paragraph (g)—Bathing, Laundry, and Hand Washing

Both TEGs and the NPRM require employers, if feasible, to provide hot and cold water under pressure in range housing. Where not feasible, employers were required to provide movable facilities for bathing, laundry, and hand washing. Only a few concerns were raised in comments on this provision.

Worker advocates requested the Department to provide workers with sun-shower devices when work is being performed in warm climates. They also asserted that employers should be required to provide workers with at least monthly access to facilities where they can have a hot shower and use of a washing machine. A few employers asserted, as discussed in connection with the minimum standard for water, § 655.235(b), that laundry facilities are unnecessary where an employer picks up and launders a worker's dirty clothes and exchanges the laundered clothes for dirty ones when it resupplies the worker. The Department is not persuaded that these suggested changes are necessary.

While the suggested use of a camp-type "sun shower" may be an economical means of allowing a worker to bathe, it is only one of several potential options that may be available to meet the employer's obligation to provide movable facilities for bathing, and there is no basis in the record for the Department to conclude that this device is superior to other methods. Allowing a range worker to obtain a hot shower and access to a washing machine each month could prove costly to an employer. We assume that the employer would have to pay for the services of a substitute worker to watch the herd in the first herder's absence, and the time and distance between the herder's work location and the available facilities might be considerable. Given that under the Final Rule's standard, the workers are provided movable washing and bathing facilities, imposing such a requirement seems unnecessary and, depending upon the time and expenses involved, could impose an unreasonable economic expense on the employer.

With regard to the suggestion that the standard should be revised in recognition that some employers launder their workers' clothes, the Department has determined that the standard should remain unchanged. It is important, in the Department's view, that workers be provided the means—tub, scrub brush, soap, and a line for clothing to dry, and a sufficient amount of water with which to launder all or some of their clothing on an as needed basis. Of course, if an employer chooses to provide laundered clothing regularly, the worker's needs are likely to be minimal.

(9) Paragraph (h)—Food Storage

Both the TEGLs and the NPRM required that employers must provide housing with mechanical refrigeration where feasible. Where mechanical refrigeration is not feasible, the standard provided the employer the choice to either provide a propane or butane-powered refrigerator or provide an alternate means by which food can be used or stored to prevent or avoid spoilage. The TEGLs mentioned salting as a method to avoid spoilage. In the NPRM, the Department proposed “dehydration” as another example of an acceptable alternative. The Department invited comment on food preservation options in keeping with food safety and nutrition concerns. These concerns have been addressed in Sec. IV.B.2.d. of this preamble, in connection with § 655.210.

As discussed with regard to the meal requirements established by § 655.210(e), commenters agreed that employers should be required to provide range workers with “adequate” meals or “sufficient” food to prepare healthy, nutritious meals and appropriate means for food storage. Insofar as food storage methods are concerned, commenters disagreed as to whether mechanical refrigeration should be required. The worker advocates suggested that the Department adopt a hierarchy of food storage methods, so that alternatives to refrigeration (*e.g.*, salting and dehydration) could only be used where such refrigeration is not possible. The worker advocates stated that advances in power options (propane located outside the unit, battery packs, and solar equipment) make refrigeration available in most instances and that their use to maintain a temperature at or below 45 degrees would allow the storage of fresh produce, thereby improving the variety and nutritional value of the workers' diets.

Employer and employer association commenters stated that while refrigeration is provided by some

employers in some locations, it cannot be provided in some remote locations (*e.g.*, in the “summer high range”) where workers must live in tents and all supplies must be transported by pack horses. Further, several commenters indicated that they must comply with Forest Service and BLM regulations, noting that in some locations the Forest Service requires food be stored in trees to minimize encounters with potentially dangerous animals. In those locations, employers stated that they provide food appropriate to the available food storage options.

Mountain Plains, Western Range and some employers, including Siddoway Sheep Company and Henry Etcheverry, read the proposal to require refrigeration units when tents are being used, an undue and likely impossible burden, because an employer's use of tents, in their view, means that the herd is located in an area where the terrain is rugged and supplies and equipment must be transported by pack horses. The Siddoway Sheep Company proposed that the purpose served by refrigeration—to ensure that workers receive nutritious meals—could be achieved by providing the workers with fresh meat and fresh produce for consumption in the short term, supplemented by a variety of canned meats, fruits, and vegetables.

The Department recognizes that range work is performed throughout the year in a wide variety of locations, including some that are remote and not accessible by motorized vehicle. Yet it remains appropriate to establish a minimum standard that is flexible enough to apply to the variety of situations on the range. The historical approach, embodied in the TEGLs and the NPRM, achieves this purpose. It allows flexibility, while at the same time ensuring that employers provide adequate and sufficient meals to workers, which cannot be met without ensuring that appropriate methods of storage are also provided.

Under the proposal and as adopted in the Final Rule, where mechanical refrigeration is not feasible, an employer may choose among alternative means to eliminate or reduce spoilage of food and thereby meet its obligations under the standard, established in § 655.210, to provide workers with sufficient and adequate meals. While the provision of a butane or propane refrigerator, obviously, would best replicate mechanical refrigeration, we conclude that requiring such use would be impractical in many instances. The Department also recognizes that in some instances, regulations by other government agencies, including those

designed to protect people from potentially dangerous encounters with wild animals, will determine appropriate storage methods. Further, as noted below in connection with § 655.235(k), employers are required to provide sealed containers for storing food where there is a risk of contamination of the food by insects, rodents, or other vermin.

(10) Paragraph (i)—Cooking and Eating Facilities

Both TEGLs and the NPRM required that if workers were permitted or required to cook in their housing, the employer must provide a space with adequate lighting and ventilation for this purpose. The TEGLs and the NPRM required that the wall surfaces next to the areas for food preparation and cooking must be non-absorbent and easy to clean. They further required that the wall surface next to cooking areas must be made of fire-resistant material. No substantive comments were received on these particular points and the Final Rule adopts the proposal without change.

(11) Paragraph (j)—Garbage and Other Refuse

Both TEGLs and the NPRM required employers to provide clean, durable, and fly-tight containers for each housing unit. If refuse and garbage cannot be buried, the employer was required to collect the garbage twice weekly or more often if necessary. The Department received only a single comment on this standard. The Siddoway Sheep Company stated that the garbage disposal requirements should be clarified because a twice-weekly schedule for removal is impractical in mountain areas, where resupply occurs only once every 8–10 days.

In the discussion above related to § 655.235(b), the Department recognized the impracticality of moving supplies in areas that are not accessible by vehicle. Similar problems are involved with the disposal of refuse and garbage by packhorse or other means. Accordingly, the Final Rule has been revised to provide a limited exception to the general requirement where garbage and other refuse cannot be buried. In those situations, the employer must collect and remove the garbage and other refuse on the return leg of its supply run. The Department reminds employers that other agencies may regulate the storage and disposal of garbage and refuse, and employers are required to comply where such regulations are applicable.

Accordingly, the text has been revised as discussed. Apart from this revision,

the Final Rule adopts the proposal without change.

(12) Paragraph (k)—Insect and Rodent Control

Both TEGLs and the NPRM required the employer to provide appropriate materials, including sprays, to combat insects, rodents, and other vermin. The Department received no comment directly on this point and the Final Rule adopts the proposal without change. A private individual, worker advocates, and employers submitted comments on protecting food from insects, rodents, and other wildlife. A private citizen, noting the difficulty of keeping insects away even in private residential areas of the country, recommended that the Department require employers to provide sealed containers to prevent insect contamination. While the Department construes its food storage and insect and rodent control standards to require this practice, the Department has determined that worker health would be better protected by making this requirement explicit. Accordingly, in the Final Rule, the Department has revised the proposal to provide: “Appropriate materials, including sealed containers for food storage, must be provided to aid housing occupants in combating insects, rodents, and other vermin” (adding underscored text).

(13) Paragraph (l)—Sleeping Facilities

The NPRM retained, with minor clarifying edits, the requirement under the TEGLs that each worker have his or her own comfortable bed, cot, or bunk with mattress. The NPRM also continued the existing variance from this requirement for temporary situations of up to three days, in which two workers could share a mobile housing unit with a single bed, provided each worker was provided his or her own sleeping bag or bedding.

Even though the Department’s intent was only to maintain the existing standard, many commenters, including Mountain Plains, Western Range, Wyoming Wool Growers, and the Texas Sheep & Goat Raisers Association, perceived the proposal as a new requirement. For example, the Colorado Wool Growers Association stated that this standard would require employers to transport a second mobile unit whenever they have two workers herding the same flock. An employer, Kay and David O. Neves, expressed the concern that the proposed standard would prevent a new herder from living in a two-bed unit with an experienced herder, denying the worker and the employer the benefit of the seasoned worker’s experience. Other commenters,

including the Texas Sheep & Goat Raisers Association also expressed concern about how the standard should be applied, *i.e.*, whether employers must provide a physically separate area for a second herder to sleep in the housing, only separate cots or beds, or only separate bedding (blanket, other linen, or sleeping bag). Mountain Plains, Western Range, and Wyoming Wool Growers requested that we remove the three-consecutive day limit on two workers sharing a unit with a single bed, stating that winter conditions and safety considerations often require two workers to care for the herd, and practical considerations prevent moving a second camper every few days. They argued in favor of revising the rule to allow two workers to share a single camper as long as there is space for two sleeping bags.

The associations and several other commenters stated that the phrase “sleeping facility” was confusing, leaving them guessing whether it refers only to a bed or the entire camp structure. The confusion caused alarm among several commenters who read the proposal to require that they must have two separate mobile housing units whenever two herders would be staying overnight at the same location. Several mentioned that this requirement would force them to purchase new units at a cost of \$20,000 per vehicle.

To remedy the concerns noted, Mountain Plains and Western Range suggested that a “sleeping unit” should be defined as “a comfortable bed, cot, or bunk with a clean mattress.” On a separate point, the worker advocates recommended that the Department revise the standard to require that mattresses and pads not sit on the floor of a housing structure and to require that if foam pads are provided, they must be thicker than two inches and covered completely with a washable material. On a related point, the Siddoway Sheep Company requested modification of the sleeping facilities standard to relieve employers of the requirement to provide mattresses or cots when workers are living in tents. It stated that its experience has been that range workers do not use the cots it has provided, preferring instead to use pine boughs.

The Department has determined that its use of the term “sleeping facility” rather than a term such as “sleeping arrangement” or even more simply “a separate bed,” to describe this standard has contributed to unnecessary confusion. “Sleeping facility,” even as defined in the TEGLs and the proposal, carries with it the idea of a physical structure, such as a camper or bunk. As

such, the standard can be read to require that whenever an employer assigns a second range worker for longer than three days to work with a another herder, it must provide a separate structure, a separate area within a single structure, or separate bed or cot, or some combination of such requirements, for each worker.

We have revised the requirement to make plain that an employer is not permitted to require workers to use or share a single bed for more than three consecutive days. It should be emphasized that the sleeping standard establishes the general requirement that each worker, on a nightly basis, must be provided his or her own separate bed. The shared sleeping exception is limited to infrequent and temporary (no longer than 3 days) situations where it is impractical to provide a worker with a separate bed, mattress, or cot. The exception cannot be used in other situations to circumvent the requirement of one worker, one bed. Of course, if the camper is designed and certified for occupancy by two people, and has two beds, two workers may occupy it.

In the Final Rule, we have revised the proposed standard to better distinguish the general requirement from the limited three-day exception.

Each worker must be provided housing (including a camper or tent, when permitted or required) that contains, except in a family arrangement, his or her own comfortable bed, cot, or bunk with a clean mattress. An employer may be permitted to require workers to use or share a single bed only where:

- The employer makes the request when filing an application for certification;
- demonstrates to the satisfaction of the CO that it would be impossible or impractical to provide each worker with a separate bed; and
- the employer provides the second worker a sleeping bag or bed roll free of charge or deposit charge.

With regard to the comment that the Department should revise the standard to relieve employers from providing a cot and mattress when workers are staying in tents, the Department disagrees. In doing so, the Department would be removing a basic measure of sleeping comfort. At the same time, it should be clear that the standard does not require a worker to use a mattress and cot if he or she prefers to sleep on pine boughs or some alternative foundation. An employer meets its obligations under the standards by making available the mattress and cot to the worker and allowing him or her to

freely choose whether or not to use these items.

As a final matter, the Department is not persuaded that it should mandate a specific thickness or covering for a sleeping pad or require an employer to modify its housing to ensure that no worker may be required to sleep on mattresses and pads that sit on the floor of the housing structure. The standard requires that the employer provide a comfortable bed, a standard that admittedly allows room for interpretation, but ensures that a worker must be provided a mattress or its equivalent, which must be clean and which provides some comfort from the alternative of sleeping directly on a hard surface. The rulemaking record does not provide sufficient information that would allow the Department to establish a particular thickness for pads, their covering, or similar particulars for bedding.

(14) Paragraph (m)—Fire, Safety, and First Aid

The NPRM continued the requirements established under the TEGs that:

- An employer must provide housing that must be constructed and maintained in compliance with applicable state or local fire and safety laws;
- the storage of flammable or volatile liquids or other materials in living areas is prohibited, except for those needed for current household use;
- the housing provide two safe means by which a worker may escape the unit without difficulty, excepting tents from the requirement of a second means of escape unless they are large and their walls are constructed of rigid material; and
- the employers must provide a first aid kit and provide adequate fire extinguishers in good working condition.

The worker advocates commented on three aspects of the proposal, requesting the Department to require employers: To install smoke detectors in housing and to provide easily accessible fire extinguishers; to require that there be an emergency exit, with egress at rear, of each housing structure; and to include particular items, as identified by the Department, in first aid kits. The worker advocates did not suggest the inclusion of any particular items, but asked the Department to consider the need for items to treat illnesses related to exposure to cold temperatures.

In the Department's view, the proposed standard adequately meets these concerns. The worker advocates have provided no evidence that the

standards are inadequate or that workers have been put at risk by the application of the standards. The proposed standard requires compliance with applicable fire and safety laws, including a second means of escape, and requires the unit to have a fire extinguisher in good working condition. The proposed language does not explicitly state that the fire extinguisher must be accessible. We have added this requirement to the standard.

Where state and local authorities have determined that smoke or fire detectors are required for the type of housing provided workers, employers must comply with those requirements. Where such laws do not apply to such housing, without any demonstration that the lack of such devices has caused injury to workers the Department is ill-equipped to mandate their use. Similarly, local and state fire departments, nongovernmental organizations, such as the Red Cross or organizations comprised of camping, hiking, or wilderness exploring enthusiasts, or their worker's compensation insurers, are better suited than the Department, at present, to recommend the items to be included in first aid kits, especially for treating injuries caused by exposure to the elements. However, we would expect that employers in stocking the required first aid kit will take into account the conditions under which range work is performed, including the risks posed by insects, wildlife, and the worker's exposure to extremes of heat, cold, storms, and rugged terrain.

We decline the worker advocates' suggestion that the Department should require employers to provide a hand-cranked generator for emergencies. They have not provided any evidence that would allow the Department to properly consider this request. With regard to their comment on first aid kits, they again have not provided sufficient evidence that would allow the Department to properly consider this request.

The Final Rule adopts the proposal on fire, safety, and first aid without substantive change. The Final Rule makes three minor changes. We have clarified that an employer must comply with both state and local fire and safety laws and that the standards apply to all housing covered by § 655.235, a change, as discussed earlier in connection with § 655.230, to make plain that stationary housing used by some employers on grazing trails must comply with the standards, which were previously referred to "mobile housing." Finally, we have clarified that employers must ensure the accessibility of fire extinguishers.

V. Administrative Information

A. Executive Order 13563 and Executive Order 12866

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

Under E.O. 12866, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of the E.O. and OMB review. Section 3(f) of E.O. 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that: (1) Has an annual effect on the economy of \$100 million or more or adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as "economically significant"); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

OIRA has designated the Final Rule a significant regulatory action under sec. 3(f) of E.O. 12866 but not an economically significant rule. The economic effects of the costs and transfers that would result from the changes in this Final Rule, above and beyond the impacts of the program as it is currently implemented, are not economically significant. The largest impact on employers will result from implementation of the wage setting methodology. The Final Rule will result in average annual transfers from employers to employees due to increased wages of \$17.46 million between 2016 and 2025, which includes

a two-year transition period during 2016 and 2017, with full implementation in 2018.^{61 62} For those employers engaged in the range production of livestock other than sheepherding and goat herding, the Final Rule requires employers to provide food or meals, free of charge, to workers at an average annual cost of \$1.78 million (employers engaged in sheepherding and goat herding must already provide free food under the TEGL, so it is part of the baseline; although employers engaged in the range production of livestock currently must provide free food based on the SWA wage survey, that could change, so we accounted for the cost). The special procedures guidance currently in place for the range production of livestock and sheepherding and goat herding require the provision of an adequate and convenient supply of water that meets the standards of the state health authority in sufficient amount to provide for drinking, cooking, and bathing. The Final Rule clarifies the required water supply by generally requiring the supply of at least 4.5 gallons of potable water per day for drinking and cooking, and modifies it by including water for laundry (with certain exceptions). The additional costs incurred by employers resulting from these requirements in the Final Rule average \$2.36 million annually and include the cost of the potable water, utility trailers, vehicle mileage, and labor to deliver the water and food to workers.⁶³ The Final Rule also includes

⁶¹ Some part of these increased wages will be paid to foreign workers. Following Circular A-4, these payments may potentially be considered costs from the perspective of the U.S. economy, but should be considered transfers if these workers can be considered "residents" of the U.S. or if the global effects of the regulatory change are analyzed.

⁶² To determine the new required monthly wage rate for 2016, the Department first multiplies \$7.25 per hour times 48 hours per week times 4.333 weeks per month. For years after 2016, the Department calculates the average change in the quarterly wages and salaries Employment Cost Index (ECI) for each year from 2012 through 2014. We then take the average year-over-year ECI growth rate and in 2017 apply the resulting value to the 2016 monthly wage, and we apply the ECI growth rate to the prior year's result again for each subsequent year. There is a transition period during 2016 and 2017, when the resulting monthly wage is multiplied times .8 and .9, respectively. This methodology is described in detail in Section 4: Subject-by-Subject Analysis. The \$17.46 million in increased wages likely is an overestimate of the impact as several employer commenters stated that they already pay wages in excess of the currently required wages (as well as for other reasons addressed in Section 4).

⁶³ The estimate of \$2.36 million is likely an overestimate based on the fact employers are already required to provide water for drinking, cooking, and bathing that meets state health standards, and it presumes delivery 50 weeks of the year when workers are only required to be on the range for a majority of the job order period.

a requirement that employers provide access to cooking and cleaning facilities when workers are located at or near a fixed-site ranch or farm. As the Department anticipates existing cooking facilities will accommodate that requirement, the estimated average annual cost to employers for costs related to the provision of cleaning facilities is \$0.75 million. The additional cost incurred by employers for recordkeeping is \$0.19 million per year and \$0.10 million for the heating equipment per year, respectively. Finally, the cost for the time required to read and review the Final Rule is \$0.01 million per year. The Final Rule involves some cost reductions for employers, primarily for those who will no longer be required to place newspaper advertisements, which amount to \$0.06 million per year. Therefore, the average annual cost of the Final Rule is \$5.13 million.

1. The Mendoza Litigation and Need for Rulemaking

In *Mendoza, et al. v. Solis et al.*, U.S. workers filed a lawsuit in the U.S. District Court for the District of Columbia challenging the special procedures for sheepherding, goat herding, and occupations involved in the production of livestock on the range, asserting that the Department violated the Administrative Procedure Act (APA) by adopting "special procedures" without first providing notice and an opportunity for public comment. The district court granted a motion to dismiss for lack of standing, but the Court of Appeals for the DC Circuit reversed the district court's dismissal and held that the Department's Training and Employment Guidance Letters (TEGLs) containing special procedures for herding and production of livestock occupations on the range constituted legislative rules subject to the APA's procedural notice and comment requirements.

Through this rulemaking, the Department is complying with an order issued by the district court on remand to remedy the APA violation found by the DC Circuit. The lawsuit, however, is only one of the reasons for the promulgation of this Final Rule. The unique on-call nature (up to 24 hours a day, 7 days a week) of the work activity in isolated areas associated with these occupations, coupled with the sustained scarcity of U.S. workers employed in herding, has made determining an appropriate prevailing wage increasingly difficult under the current methodology for determining wages for these occupations. In these occupations, the prevailing wage serves as the

Adverse Effect Wage Rate (AEWR). Few employers provide U.S. worker wage information in response to prevailing wage survey requests for these occupations, making it difficult for State Workforce Agencies (SWAs) to submit statistically valid prevailing wage findings to the OFLC Administrator. For example, based on a review of employer surveys conducted over the last four years by approximately 10 states located in the mountain plains/western regions of the United States, all of the SWAs with reportable wage results under ETA's guidelines reported a combined total of only 30 (2012), 26 (2013), 18 (2014), and 52 (2015) domestic workers performing sheepherding; these numbers are insufficient to report statistically reliable wage results by state. Therefore, through this rulemaking, the Department plans to establish a more effective methodology for determining and adjusting a monthly wage rate for these unique occupations that adequately protects U.S. and H-2A workers in these occupations. In addition, the Department has received complaints concerning housing conditions and has found violations of the housing standards in both complaint and directed (non-complaint) investigations. In addition, several cases have been litigated in which workers' health and safety were at question. See *Ruiz v. Fernandez*, 949 F. Supp. 2d 1055, 1060 (E.D. Wash. 2013) (denying defendants' motion for summary judgment where plaintiff-sheepherders alleged mistreatment, including denied breaks, threats of deportation, inadequate food, and housing that did not meet the minimum health and safety standards); *Camayo v. John Peroulis & Sons Sheep, Inc.*, No. 10-CV-00772-MSK-MJW, 2012 WL 4359086, at *1 (D. Colo. Sept. 24, 2012) (denying defendant's motion to dismiss where plaintiff-sheepherders alleged severe mistreatment, including lack of food); *In the Matter of: John Peroulis & Sons Sheep, Inc.*, ALJ Case No. 2012-TAE-00004 (appeal pending before ARB) (ALJ upheld the Department's charges against employer for multiple violations, including lack of adequate housing).

2. Regulatory Alternatives

In the Notice of Proposed Rulemaking (NPRM), the Department proposed to set the monthly AEWR for these occupations based on forecasted AEWR values from the Farm Labor Survey conducted by U.S. Department of Agriculture USDA (FLS-based AEWR) multiplied by an estimate of 44 hours per week, with a four-year transition and full implementation in year five (referred to in the NPRM as a five-year

phase-in). In addition, DOL considered the following two alternatives: (1) Base the monthly AEWR on the FLS-based AEWR multiplied by 44 hours with a two-year transition and full implementation in year three; or (2) base the monthly AEWR on the FLS-based AEWR multiplied by 44 hours with no transition.

The Department received numerous comments related to the alternatives considered in the NPRM's EO 12866 analysis. Many commenters, including Mountain Plains Agricultural Services and Western Range Association (Mountain Plains and Western Range) and the Texas Sheep & Goat Raisers Association, as well as Brent Espil, Cunningham Sheep Co., and Siddoway Sheep Company, Inc. (individual employers) asserted that the alternatives were not "true" alternatives in that the Department did not consider other ways to determine the AEWR for occupations involving the herding or production of livestock on the range. For this reason, some commenters stated that the Department failed to meet the requirements set forth in the Regulatory Flexibility Act (RFA). They characterized the three alternatives presented by the Department as one alternative with three transition periods methods, and stated that in their view the alternatives therefore do not satisfy the requirements of Section 603(c) of the RFA to describe "any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." The U.S. Small Business Administration (SBA) Office of Advocacy similarly asserted that the Department did not analyze any regulatory alternatives that may minimize the economic impact of the proposed rule on small businesses, and suggested that the Department publish a Supplemental Initial Regulatory Flexibility Analysis (IRFA). The Wyoming Farm Bureau Federation—a trade association—questioned why the Department did not consider longer phase-in alternatives. In the Final Rule, the Department analyzes a different set of alternatives that utilize different wage rate sources, including the Fair Labor Standards Act (FLSA) current minimum wage of \$7.25/hour, the 1994 TEGL monthly wage rates indexed by the Employment Cost Index (ECI) for wages and salaries as published by the Bureau of Labor Statistics (BLS), and the FLS-based AEWR.

The Department carefully reviewed the comments related to the proposed wage setting methodology and to the

alternatives laid out in the E.O. 12866 analysis and the IRFA. After considering the comments, the Department has decided to set wage the monthly AEWR for range herders of sheep, goats, and other livestock using a formula based on the current FLSA minimum wage of \$7.25/hour as a starting point, multiplied by a revised weekly estimate of 48 hours per week, with annual adjustment based on inflation from the ECI for wages and salaries beginning in year two. This base wage source is generally consistent with the second of two alternative proposals set forth by Mountain Plains and Western Range, which was endorsed by the ASI and many individual employers. DOL adopts a weekly hour estimate of 48, which is greater than that proposed by these commenters, and a transition period (two years with full implementation in year three) shorter than that favored by these commenters. As under the proposal, the employer is required to pay an applicable Federal or State minimum wage if higher than the monthly AEWR. As discussed in detail in the preamble, the Department concludes that this wage rate is both necessary to provide a meaningful test of the labor market for available U.S. workers and to protect against adverse effect on workers in the United States similarly employed.

As discussed in the Final Regulatory Flexibility Analysis (FRFA) that follows, in addition to the wage methodology adopted in this Final Rule, the Department considered three alternative methods to set the monthly AEWR: (1) To set the monthly AEWR based on the 1994 TEGL wage adjusted for inflation using the capped ECI,⁶⁴ and a three-year transition period with full implementation in year four; (2) to set the monthly AEWR based on an hourly rate of \$7.25 multiplied by an estimate of 44 hours per week and adjusted using the capped ECI beginning in year five, implemented with a three-year transition period with full implementation in year four; and (3) to set the monthly AEWR using the FLS-based AEWR multiplied by an estimate of 65 hours per week without a transition and permitting food deductions based on the methodology used in the rest of the H-2A program.

⁶⁴ Mountain Plains and Western Range recommended indexing past wages based on the ECI with a 1.5 percent adjustment if the percentage increase in the ECI during the previous calendar year was less than 1.5 percent; by the percentage increase in the ECI if such percentage was between 1.5 percent and 2.5 percent, inclusive; or by 2.5 percent if the percentage increase in the ECI exceeded that amount. We refer to this methodology throughout as the "capped ECI".

The selected methodology will most effectively enable the Department to meet its statutory obligations to determine that there are not sufficient workers available to perform the labor or services requested and that the employment of foreign workers will not adversely affect the wages and working conditions of workers in the United States similarly employed before the admission of foreign workers is permitted. The new wage methodology will begin to address immediately and substantially the wage stagnation concerns discussed earlier in the preamble. The transition period recognizes that the full wage increase in a single year could lead to disruptions that could be avoided by the more gradual implementation period. In determining where to set the monthly AEWR so that it will not result in adverse effect, it was appropriate for the Department to consider whether a significantly higher wage could be immediately absorbed by employers or might have the unintended consequence of reducing the availability of jobs for U.S. workers because the wage would result in some employers going out of business or scaling back their operations, as a substantial number of comments demonstrated.

3. Economic Analysis

The economic analysis presented below covers employers engaged in the herding or production of livestock on the range. The Department's economic analysis under this Part (III.A) is strictly limited to meeting the requirements under Executive Orders 12866 and 13563. The Department did not use the economic analysis under this Part as a factor or basis for determining the scope or extent of the Department's obligations or responsibilities under the Immigration and Nationality Act, as amended. Nor did the Department use the economic analysis in this Part as a relevant factor relating to any requirement under the Administrative Procedure Act (APA), or any case interpreting the requirements under the APA.

The Department derives its estimates by comparing the baseline, that is, the program benefits and costs under the 2010 Final Rule and TEGLs 32–10 (*Special Procedures: Labor Certification Process for Employers Engaged in Sheepherding and Goatherding Occupations under the H-2A Program*) and 15–06, Change 1, (*Special Procedures: Labor Certification Process for Occupations Involved in the Open Range Production of Livestock under the H-2A Program*), against the benefits and costs associated with the

implementation of provisions contained in the Final Rule. This analysis assumes that entities subject to the Final Rule are already in compliance with the 2010 Final Rule and relevant TEGLs. We explain how the required actions of employers engaged in herding or the production of livestock on the range are linked to the expected impacts of the Final Rule.

The Department has quantified and monetized the impacts of the Final Rule where feasible. Where we were unable to quantify benefits and costs—for example, due to data limitations—we describe them qualitatively and identify which data were not available to quantify the costs. The analysis covers 10 years (2016 through 2025) to ensure it captures all major impacts.⁶⁵ When summarizing the benefits, costs, or transfers resulting from specific provisions of the Final Rule, we present the 10-year averages to estimate the typical annual effect or 10-year discounted totals to estimate the present value of the overall effects.

In the remaining sections, the Department first presents an overview of general comments received from the public. We then present a subject-by-subject analysis of the impacts of the Final Rule and a summary of the costs and transfers, including total impacts over the 10-year analysis period.

a. General Comments Received on the Economic Analysis

i. Employer Growth Rate

The NPRM's EO 12866 analysis used an annual growth rate of 2 percent to forecast participation in the H-2A program. Several commenters stated that this growth rate was inaccurate. Carol Martinez, Alex (Buster) Dufurrena, and John and Carolyn Espil, individual employers, stated that the assumed 2-percent annual growth rate of U.S. sheep producers was inaccurate because the proposed rule would put additional financial burdens on producers that would force them to reduce the number of H-2A workers hired or to close. John and Carolyn Espil referenced the BLS Occupational Outlook Handbook (2014–15 Edition), which predicted that farmers, ranchers, and other agricultural managers would experience a loss of 179,000 jobs over the period of 2012–2022, which amounts to a 19 percent reduction. Similarly, the Texas Sheep & Goat Raisers Association and ASI and Public Lands Council stated that after the National Wool Act was phased out by the Federal government in 1993–1995, tens of thousands of sheep

ranches went out of business and subsequently, in the late 1990's, linked allied industries also went out of business due to the lack of lamb and wool. Mountain Plains and Western Range stated that the assumed 2-percent employer growth rate “demonstrates how fundamentally wrong DOL's assumptions are.”

The Department had estimated the 2-percent annual growth rate based on historical H-2A program data on labor certifications for sheepherding, goat herding, and range cattle production employers. For the Final Rule, the Department updated its analysis by evaluating the annual change in the number of unique herding employers between FY 2012 and 2014 and found inconsistent results. Between FY 2012 and 2013, we found a decrease in participation of 114 percent, while the FY 2013 and 2014 program data indicate an increase in participation of 11 percent. In light of the comments and this data, in the Final Rule the Department revises the growth rate to be 0 percent, that is, the Department assumes the employer participant population in this H-2A program will neither rise nor fall over the analysis time period.

ii. Comments Received on Impacts on Profitability

Several commenters stated that the increased costs associated with the proposed rule, particularly the proposed wage increases, would destroy the industry. Other commenters questioned the accuracy of the economic analysis and opposed some of the conclusions presented in the analysis. For example, Representative Allen Jaggi, an elected official, and Skye Krebs, an individual employer, warned that the proposed rule would force employers out of business because they operate on thin profit margins. The American Farm Bureau Federation used an industry standard range sheep farm budget developed by the University of Utah to analyze the impact of the proposed 2020–2025 forecasted FLS-based AEWR wage, which resulted in \$41,325 per year in additional wages. According to the American Farm Bureau, if prices fall to year 2002 conditions—the lowest prices over the period of 2000–2014 (\$0.80 per pound for lambs and \$0.53 per pound for wool)—employers in each of the 19 states analyzed would be operating at a loss (Alabama, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Missouri, Montana, New Mexico, Nevada, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming). They also presented the average prices over the

last five years as well as over the preceding 10 years to demonstrate the trend in prices. They noted that the average price received for lamb over the past five years (\$1.70 per pound) is 63 percent higher than the price received over the preceding 10 years (\$1.04 per pound), while the average price received for wool over the last five years (\$1.45 per pound) is 113 percent higher than the prices they received on average over the preceding 10 years (\$0.68 per pound). The State of Utah also submitted data pertaining to the average price of lamb over time. The State noted that the average price of lamb increased from \$67.94 in 1994 to \$157.15 in 2014, which amounts to an increase of \$48.61 over a 20-year period after adjusting for inflation. Without acknowledging that worker wages have not similarly been adjusted for inflation, the commenter stated that this small increase in the value of lamb cannot support the proposed tripling in the wage increase and will force producers out of business.

The Utah Farm Bureau Federation, the Texas Sheep & Goat Raisers Association, and Mountain Plains and Western Range analyzed an enterprise budget for an Idaho sheep operation with ewes on the range and selling feeder lambs (Painter, K., Idaho, University of Idaho, 2014), which earned \$60 per head in total returns. Using data for the State of Utah, the Utah Farm Bureau estimated that after tripling the wage rate, total returns would decrease 111 percent to negative \$6.00 per head, while income above operating costs would decrease 80 percent from \$83,000 to less than \$17,000. They stated that tripling the hired labor rate reduces total returns from a profit of nearly \$90,000 to a loss of approximately \$10,200.

The Wyoming Wool Growers Association stated that the Department underestimated the cost associated with the proposed wage increase. They referenced an analysis from the University of Wyoming estimating that the proposed wage increases would increase the annual operating costs by more than 40 percent (\$39,600) for a Wyoming range sheep operation with two foreign herders. The analysis also indicated that income above operating costs would fall by 78 percent (to \$11,313) under current price conditions. The Texas Sheep & Goat Raisers Association commented that the Department underestimated the cost of the proposed rule, which included the cost of additional wages over the period from 2016 to 2020 (\$45 million) and non-wage costs (\$5 million per year).

⁶⁵ For the purposes of the cost-benefit analysis, the 10-year period starts on January 1, 2016.

John and Carolyn Espil stated that the Department misrepresented the make-up of the industry as it was presented in the NPRM's Exhibit 2 (The Number and Percentage of H-2A Employers by Occupation and State). They stated that none of the values in the Exhibit reflected the Western Range Association's membership numbers. For example, the Department presented information indicating that Nevada had one employer, while the Western Range Association had 17 members from Nevada as of January 2015. Because of what they perceived as an inaccuracy, they questioned the overall accuracy of the economic analysis. They also disagreed that the proposed rule was not a major rule that required review by Congress under the Small Business Regulatory Enforcement Fairness Act (SBREFA), asserting that it would have an economic impact of at least \$100 million and would result in increased costs to consumers, levels of government, and regions due to failed businesses, the loss of stewardship of the land by livestock workers, as well as a loss of 40 percent of the sheep industry. They stated that this would affect competition, employment, investment, productivity, innovation, and the competitiveness of U.S.-based businesses.

Mountain Plains and Western Range, and Vermillion Ranch and Midland Ranch stated that the economic analysis did not take into account the cost of forcing ranches to close or to downsize. The commenters contended that employers would be forced to sell their herds, equipment, and land into a buyer's market. Many other commenters similarly stated that the economic analysis did not estimate the losses associated with the massive sale of livestock. Since 40 percent of the nation's sheep graze on ranges, the commenters asserted that the proposed rule could lead to the sale of breeding ewes for slaughter at undervalued prices because the market would not be able to absorb them. Mountain Plains and Western Range, for example, estimated that the total loss would be \$212 million based on the total value of the U.S. sheep supply. They also emphasized that the ranchers could not simply raise prices to cover the increased costs because U.S. producers account for less than seven tenths of one percent of the world's wool production and less than nine tenths of one percent of the world's lamb production.

The commenters focused primarily on the proposed wage increase because labor is such a significant percentage of their operating costs, although the statistics they cited were not uniform.

The Utah Farm Bureau Federation referenced an economic analysis conducted by Dr. Julie Shiflett of Juniper Consulting, which stated that hired labor accounts for 40 percent of total operating costs for an average western range sheep operation with two bands of sheep. The Rural Development Office cited the Utah Woolgrowers Association, which also stated that labor costs make up 40 percent of total operating costs in Utah sheep operations.

On the other hand, the Wyoming Livestock Board, the Texas Sheep & Goat Raisers Association, Mountain Plains and Western Range, and ASI and Public Lands Council summarized that current statistics from ASI show that, on average, hired labor costs make up 24 percent of a sheep rancher's total operating costs. The Diamond Sheep Company stated that wage costs represent approximately 20 percent of its operation's annual costs. The commenter noted that, in total, nearly 30 percent of its annual operating costs are labor-related when groceries—which make up approximately five percent—and travel and labor document fees—which make up 2 percent—are included.

Several commenters described the effect the proposed rule's wage increases would have on their operations, with some indicating that the proposal would result in annual operating losses:

- FIM Corp. stated that over the period of 2006–2013, its gross annual income from sales of wool, lambs, sheep, and hay averaged \$1.1 million and that after operating expenses are taken out, its net income averaged approximately three percent of gross income. FIM Corp. further stated that the proposed tripling of shepherd wages would result in approximately \$250,000 per year in additional wage payments. The commenter also noted that it employs 11 H-2A shepherders and seven workers for other ranch work, and stated that it treats them equally; hence, it would apply any wage increase imposed by the Department to all workers, which would cost the commenter's operation between \$320,000 and \$450,000 per year.

- David and Bonnie Little stated that they typically employ 10 shepherders and that the proposed wage increase would add an additional \$180,000 per year in payroll expenses, which exceeds their average adjusted gross income of \$79,000.

- Steve Raftopoulos, an individual employer, stated that the proposed wage increase alone would result in a loss of

approximately \$120,000 in 2017 and \$320,000 by 2020.

- The Siddoway Sheep Company stated that the proposed wage increase would result in increased costs of \$98,354 over the first five years of implementation, excluding employer liability for payroll taxes, while using the FLS-based AEW with no transition would result in increased costs of \$138,539 over the first five years of implementation. Siddoway stated that the wage increases should be consistent with average wage growth, and stated (without noting that there has been almost no wage growth for H-2A herders since 1994) that the average wage for U.S. workers increased 3.13 percent in 2011, 3.12 percent in 2012, and 1.28 percent in 2013.

- Eph Jensen Livestock, LLC stated that, in 2014, wages paid to shepherders accounted for nine percent of the gross revenue and would have accounted for as high as 30 percent if the proposed rule had been fully implemented.

In contrast to the comments from employers, the Worker Advocates' Joint Comment emphasized that the proposed monthly wage was inappropriately low. They criticized the weekly number of hours used to set the proposed monthly wage, presenting data from a survey of 90 H-2A herders indicating that only 7 percent worked less than 60 hours per week, while 62 percent worked more than 81 hours per week, and 35 percent worked more than 91 hours per week. In their view, this study demonstrates that the 44-hour assumption used in the proposal is a significant underestimate of the actual number of hours worked. In support of the view that the FLS-based AEW should be immediately effective, the Worker Advocates' Joint Comment pointed to several examples of jobs that, in their view, demonstrated that the ranching industry already supports workers earning the full FLS-based AEW who perform similar work, particularly citing "Sheep, Farmworker General" in Wyoming, "Closed Range Herders" in Texas, and ranch hands performing livestock as well as other tasks. They further cited wage rates paid by employers "in states without large herder populations," such as for Maine sheep farmers and sheep farm workers in North Dakota (both paid on an hourly basis). Further, they noted that California, where employers are significant participants in the H-2A program, has a wage rate for herders that is significantly higher than the current TEGL wages in other States.

In response to the comments on potential economic losses to H-2A employers attributable to the proposed

rule, the Department considered enterprise budgets pertaining to range sheep production submitted by commenters and the economic analysis provided by the American Farm Bureau on the range sheep production industry, in assessing the industry's ability to absorb the increased wages that would have been required based on the FLS-based wage methodology in the proposed rule.⁶⁶ The Department also considered the comments from individual employers who provided the data on wage increases as a percentage of their revenues and profits. We also reviewed the historic pricing data for lamb and wool, which show significant fluctuations over the years. The Department also carefully reviewed the comments from worker advocates regarding the wages paid in occupations that they view as comparable to range herding jobs and the hours worked.

After carefully evaluating all of the available information, we found that the data did not warrant setting wages for these occupations based on the FLS-based AEWR for the reasons discussed in detail in the preamble and summarized below. If the rule would result in a substantial number of range herding employers closing their operations or significantly reducing the number of workers hired, that would result in fewer jobs being available to U.S. workers and would thus be inconsistent with the Department's obligation to protect against adverse effect to U.S. workers.

First, the Department received many comments from employers who have been in the business for many generations asserting that the proposed wage rate would cause many employers to either go out of business entirely or to downsize and greatly reduce the number of workers employed. Commenters provided enterprise budgets for the range sheep production firms in Wyoming, Idaho, and Utah.⁶⁷ The enterprise budgets for range sheep production show that applying the full FLS-based proposed AEWR to H-2A

workers will lead to a wage increase of about 290 percent, which under the conditions presented will entirely eliminate profits in Wyoming and Idaho and substantially diminish them in Utah. For example, the Wyoming Wool Growers Association estimated that the proposed wage increase would reduce annual returns to a negative \$16,237. The commenter asserted that based on the past 20 years of total receipts per ewe, the sheep operation would have been able to pay total operating and ownership costs only eight percent of the time over the 20-year period if labor costs were as high as proposed by the Department.

The American Farm Bureau, using the average prices for 2000–2014,⁶⁸ showed that the profit for range sheep firms will be reduced by approximately 35 percent to 40 percent in Utah, Colorado, Nevada, Wyoming, and Idaho. The reduced profits are approximately \$75,000 on average per firm in those states. When the 2002 prices are used, which were the lowest over the 15-year period, profits for range sheep production firms in all five states will be entirely eliminated. The American Farm Bureau stated that the historic prices for feeder lamb and shorn wool have fluctuated greatly over the last 25 years and that it is probable they will return to prices lower than the current prices, which in the past few years have been at historic highs.

Nevertheless, after considering variations from year to year, the data reflect that the increases in the prices of wool and lamb have outpaced the minimal increases in wages, and that based upon the 15-year average prices a substantial increase in wages could be absorbed. Thus, even the three primary employer associations have proposed setting the monthly AEWR based on a methodology that will result in wages significantly above the current TEGL rates, which we view as compelling evidence that the industry will remain viable even where employers pay a significantly higher wage rate to employees in these occupations. This is consistent with the fact that employers in Oregon and California are currently paying substantially higher wages (for example, in California the higher state minimum wage for sheepherders produces a monthly salary for sheepherders of \$1,600.34, and effective January 1, 2016 it will increase to \$1,777.98). Not only does the industry remain viable at those rates in those States, but California has the second highest number of employers

participating in the H-2A sheep and goat herder program.

This evidence is supported by the few comments we received in support of the proposed wage methodology in the NPRM. These commenters stated that wage rates based on the full FLS-based AEWR, as in the proposed rule, are appropriate and necessary to protect against adverse effect on workers in the U.S. similarly employed. The Worker Advocates' Joint Comment provided prevailing wage data for various states based on wage surveys that show that some H-2A workers performing similar duties are paid at wage rates that are comparable to the full AEWR.

However, as discussed in the preamble, DOL found that data did not warrant setting wages for these occupations based on the FLS-based AEWR. The record indicates that the proposed approximate tripling in the wage rates, which would have resulted in higher wage rates than those in California in several states, could not be absorbed without a significant risk of job losses. Based on the comments from ranchers, the Department concludes that at least some sheepherding or goat herding employers would decide to leave the industry if, due to the extra costs, they would be able to earn income outside farming that is significantly higher than their reduced profits or no profit, especially due to the risky and unpredictable nature of agriculture and the fluctuations in prices that they receive with an ever-decreasing share of the world market. Therefore, we conclude that some ranchers would not be able to continue to do business if they had to pay H-2A workers at the FLS-based AEWR, thereby resulting in job losses in the range sheep production industry and related industries.

As noted above, the Department relied on the enterprise budget data submitted by commenters only in conjunction with all the other information in the record in coming to this conclusion, because there are several limitations on that data. First, the enterprise budget data is not available for all range sheep production firms in terms of various operational sizes and geographical areas, which are factors that may significantly affect costs and profitability. Second, budgets are generally constructed to reflect future actions, and it is difficult to accurately predict future commodity prices and yields. High degrees of variability in price and production adversely affect the reliability of the estimates used in the enterprise budgets. Third, it likely that some of the workers included in the enterprise budgets are paid wages above those required by the TEGLs; therefore,

⁶⁶ As discussed below, the enterprise budgets are from various years when labor, lamb, wool and all other factors were priced at different levels, making them of somewhat limited utility; however, they provided a useful starting point for the analysis.

⁶⁷ Wyoming Wool Growers Association, "Economic Importance of Sheep Production in Wyoming," http://wyowool.com/NewsandInfo/2015/Supplemental%20Info_UWYO%20Analysis_EconImpactSheep%20in%20WY.pdf; University of Idaho Extension, "2014 Idaho Livestock Costs and Return Estimate—Sheep Range," <http://web.cals.uidaho.edu/idaohogbiz/files/2015/04/EBB-SR1-14.pdf>; Utah State University, *Extension Economics*, E. Bruce Godfrey and Gary Anderson, <http://extension.usu.edu/agribusiness/files/uploads/livestock/pdf/1997%20range%20sheep.pdf>.

⁶⁸ \$1.26/lb 60–90 pound feeder lambs, \$0.90/lb shorn wool.

the wage increase costs measured in this analysis may overestimate the true cost increase for H-2A employers.⁶⁹ In addition, errors in developing an enterprise budget from various data sources can compound themselves to the point where budgets can have limited value in assessing profitability and break-even values, particularly for range sheep production. Finally, a rancher could have multiple enterprise operations that include both range sheep production and range cattle production. This would negate the accuracy and reliability of the profitability analysis of the rancher that is solely based on the enterprise-budget data pertaining to range sheep production.

In that regard, the Department did not receive any economic analysis pertaining to range cattle production, which is a much smaller part of the program than the range production of sheep; the limited data received for cattle herding is generally consistent with that received on sheep production. For example, Vermillion Ranch and Midland Ranch, individual employers, provided a link to a study⁷⁰ showing that the average net income (*i.e.*, profit) for range cow/calf production is 55 cents per acre in New Mexico and also indicated that a cow/calf operation running 300 head in New Mexico would need about 31,000 acres. Using 31,000 acres for a viable range cattle production firm in New Mexico, it would have an annual profit of \$17,050. This profit would be reduced by almost 90 percent to around \$1,700 if wages were increased by 250 percent based on the monthly FLS-based AEWR for one H-2A worker hired by the firm.

The Department understands that prices for wool and lamb have varied widely over the past 15 years, and that they are currently at historic highs, so that in determining the appropriate wage rate we cannot consider only what employers presently can pay without resulting in the loss of jobs. Based on the record in the comments as a whole, the Department concludes that some ranchers would not be able to continue to do business if they had to pay H-2A workers at the full FLS-based AEWR, as proposed; thus, there would be a potential for significant job losses in the

range sheep, goat and cattle industries and related industries. Therefore, the Department modified the required monthly AEWR in the Final Rule in a manner generally consistent with a suggestion offered by Mountain Plains and Western Range and many other commenters, although modified in a manner suggested in the Worker Advocates' Joint Comment. Thus, the Department has decided to set wage rates for range sheep, goat and other livestock herders based on a formula that uses the current FLSA minimum wage as a starting point and updates it annually for inflation. These rates are in line with those set forth in the second of two alternative proposals by Mountain Plains and Western Range, a proposal that was endorsed by ASI and many individual employers. However, we modify their suggestion by increasing the number of hours in setting the monthly rate to 48 hours per week, and by shortening the transition period before the full monthly AEWR goes into effect. The record, including the comments from the three primary employer associations, demonstrate that such higher wage rates can be absorbed and will not result in significant job losses. In addition, the viability of these higher wage rates is supported by the fact that California has continued to have a vibrant herding industry (it is the second largest user of the H-2A herder program) even in light of the increased wage rates in that state. The Department concludes that the increase in operating costs under the new wage rate initially based on the FLSA should be manageable for ranchers and is the minimum necessary to overcome the decades of wage stagnation and require that the job opportunities are made available to U.S. workers at appropriate wage rates that will not result in adverse effect.

iii. Economic Impacts of Herding on Other Industries

The Department received numerous comments related to the economic impacts of herding on other industries. Many commenters asserted that up- and down-stream businesses in related industries, consumers, as well as local, state, and national economies would be negatively affected by the implementation of the rule.

Several commenters, including ASI and Public Lands Council, the Texas Sheep & Goat Raisers Association, and individual employers, stated that since 38 percent of U.S. sheep are cared for by H-2A workers, if the proposed rule forced ranchers out of business, it could result in up- and down-stream losses. The Texas Sheep & Goat Raisers

Association, ASI and Public Lands Council, and the Utah Farm Bureau Federation estimated that, in 2014 dollars, \$1.00 of revenue produced by a sheep producer generates \$1.71 in backward-linked industries and \$0.80 in forward-linked good and services industries, for a total of \$3.47 in additional economic impacts generated in the local, rural economy (Shiflett, ASI, Sheep and Lamb Industry Economic Impact Analysis, April 2008, Revised March 2011). They stated that the U.S. sheep industry annually generates approximately \$500 million in backward-linked industries through the sale of items such as lambs, wool, and cull breeding stock. The direct and value-added multiplier effects were calculated to be an estimated \$486.5 million, which supports an additional \$1.2 billion in economic activity for a total of \$1.7 billion. The sheep industry also supports forward-linked industries, such as local businesses, through expenditures of sheep-industry generated income on goods and services. Estimates of sales from retail lamb and wool-related products indicate that \$785.6 million in production generates an additional \$1.9 billion in multiplier effects. The commenters stated that the total economic impact is \$2.7 billion. Mountain Plains and Western Range stated that the estimated value of the direct production of sheep cared for by H-2A workers is \$275 million, and that revenue created in indirect up- and down-stream businesses is valued at more than \$665 million.

The Texas Sheep & Goat Raisers Association and ASI and Public Lands Council further remarked that an estimated loss of \$66,167 per rancher would generate approximately \$229,320 in backward- and forward-linked businesses, and given that they estimate 598 operations employ herders, rural communities across the West would experience a loss of approximately \$137.1 million. The commenters stated that a loss of over \$66,000 per sheep rancher would result in 1.67 jobs being lost at the ranch, which would subsequently result in a total loss of 2.62 jobs in the local economy. They estimated that if 598 sheep operations employing herders suffered this loss, the total rural-employment loss would be 1,568 jobs.

Many commenters, including the Texas Sheep & Goat Raisers Association, the Wyoming Livestock Board, the Wyoming Wool Growers Association, the National Lamb Feeders Association, the Garfield County Farm Bureau, and TVB Management Company, discussed the broader impact of the rule. Some

⁶⁹This is particularly true as the budgets are not limited to H-2A workers, and some employers stated in their public comments that they pay even their H-2A herding workers above the minimum TEGL-required wage.

⁷⁰New Mexico State University, Cooperative Extension Service Agricultural Experiment Station, "Legacy of Agricultural Property Tax in New Mexico (2011)," http://aces.nmsu.edu/pubs/_ritf/RITF81.pdf.

cited industry estimates that suggested that each H-2A open-herder position creates many full-time U.S. jobs up- and down-stream, most of which are associated with small, rural communities. Mountain Plains and Western Range stated that significant losses would occur up-stream and down-stream, because each production of livestock job creates at least eight full-time U.S. jobs. Commenters cited related industries and jobs such as feed suppliers, lamb processors, slaughterhouses, meat packing plants, truck drivers, shearers, textile mills, fencing companies, veterinarians, supermarket clerks, and butchers who would be affected. Other commenters focused on the types of supplies and equipment that sheep businesses typically buy from local businesses (e.g., groceries, propane, campers, animal feed, crop seeds, cloth, insurance, medicine, parts from agriculture dealers and auto part stores, as well as vehicles and machinery such as ATVs and John Deere and Bobcat products). The commenters warned that the effects would not be limited to western sheep operations—the loss of the supporting industry in the West would force eastern sheep operations out of business as well. They noted that losing 2,000 H-2A workers could result in the loss of tens of thousands of U.S. jobs.

Some commenters from supporting businesses expressed how the proposed rule would affect them. Below are three comments that were typical of the comments provided:

- Oregon Shepherd LLC, which manufactures all-natural wool building insulation, stated that it is a small business with three employees that depends on the U.S. sheep industry for raw materials. It is located in a rural Oregon county with a higher than average unemployment rate.
- Center of the Nation Wool, Inc. is a primary wool supplier to the U.S. textile industry and acts as a wool marketing agent for a large percentage of sheep enterprises, which are mostly small family operations that would be directly affected by the proposed rule. The commenter asserted that the implementation of the proposed rule could lead to a loss of textile jobs and destroy the entire lamb and wool marketing chain.
- Mountain State Rosen, LLC is an integrated lamb packer and processor. It employs over 300 people and has national distribution with annualized sales of \$192 million. It is a producer-owned company affiliated with Mountain States Lamb Cooperative, which is comprised of 170 lamb producers located in 17 western states,

and 65 percent of the lambs they market through their cooperative come from ranches with H-2A herders. The commenter stated that volume is critical to its business, and the proposed rule would force mass liquidation of western sheep operations, thereby doing significant harm to its business.

The New Mexico Department of Agriculture, the Wyoming Department of Workforce Services, the Wyoming Department of Agriculture, Governor Matthew H. Mead of the State of Wyoming, and John and Carolyn Espil suggested that the Department should perform a full economic analysis on the impacts that the proposed rule would have on local, State, and national economies. ASI and Public Lands Council stated that for some western states (e.g., Idaho, Colorado, Oregon and New Mexico), the loss of sheep-related economic activity would affect three to five percent of the total agriculture, forestry, fishing, and hunting gross domestic product (GDP). For other western states, the loss would be more significant—for example, sheep-related economic activity accounts for 14 percent of the GDP in Utah and Wyoming. The Lassen County Board of Supervisors stated that the value of sheep and lamb livestock production (\$1,332,634) made up approximately 25 percent of Lassen County's 2012 agricultural economic output. Vermillion Ranch and Midland Ranch stated that Vermillion Ranch holds grazing permits in Daggett County, Utah, and pays property taxes; hence, it is a critical part of the local economy (as are other ranches throughout western States). John and Carolyn Espil stated that Bureau of Land Management (BLM) and Forest Service sheep permits would be rendered valueless.

Other commenters expressed concern that the proposed rule would result in shortages of lamb and wool, because U.S. citizens could not afford or would not be willing to pay higher prices for lamb and wool. A consultant to ASI for military procurement stated that the proposed rule would disrupt the wool industry's ability and requirement (by the Berry Amendment) to support the U.S. Department of Defense (DOD) with wool for garments and blankets. The commenter stated that over 80 percent of the wool required by DOD is grown in the West on lands requiring shepherds. If domestic wool production is reduced by 38 percent, it may be impossible for the national industry to supply DOD. The commenter cited FY 2015 DOD-published accession, retention, and clothing issue rates, which indicate that DOD would spend over \$300 million on wool-based

garments and blankets in FY 2015. The commenter asserted that this expenditure could support as many as 5,000 manufacturing jobs in the U.S. economy, which may be lost if the proposed rule were implemented.

The Department is unable to accurately quantify the potential indirect economic impacts to related industries in the local and national economies, due to the lack of data and economic models necessary to conduct an appropriate analysis. Therefore, the Department estimated the costs only to the sheep, goat and range cattle production industries that are directed affected by this regulation, both in the NPRM's EO 12866 analysis and IRFA and in the Final Rule's analyses. In the absence of an economic input-output model or comparative general equilibrium model of the economy specifically developed for sheep, goat and range livestock production industries, it is not possible to measure the aggregate indirect economic impact of the Final Rule on other related industries in the economy with any degree of accuracy.

Numerous changes made in the Final Rule make these commenters' concerns about the impact on the broader economy unlikely. These include for example, the adoption of a definition of "range" that deletes the reference to fencing that so many commenters opposed, the adoption of a wage setting methodology that is similar to a suggestion offered by the three primary employer representatives, and the other flexibilities such as the deletion of the proposed 20 percent cap on the days that workers could perform duties at the ranch that are closely and directly relating to herding and/or the production of livestock. The Department concludes that the Final Rule will not likely result in the commenter predictions regarding the impact on the broader economy.

The Department also is responding to a few other specific comments that we received. John and Carolyn Espil stated that the Department misrepresented the make-up of the industry as presented in Exhibit 2 of the NPRM, which showed the number and percentage of H-2A employers by occupation and state derived from H-2A employer applications filed with the Department during FY 2011 and 2012. The Exhibit was not intended to reflect the total number of employers in the industry in Nevada as of January 2015 or the number of members of the Western Range Association. In the Final Rule, the Department has updated the number of H-2A employers by state using H-2A employer applications filed during FY

2013–14. The Exhibits below present the number of unique herder and range livestock production employers by state for FY2013 and 2014. However, due to

the fact that these occupations involve performing work on itineraries covering multiple states, some employers applied for certification covering areas of

employment in multiple states; thus, the total number of unique employers is overstated.

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EXHIBIT 1: NUMBER OF SHEEP AND GOAT HERDER EMPLOYERS			
State	2013	2014	Average
AL	2	2	2
AZ	166	169	168
CA	133	171	152
CO	56	44	50
HI	2	2	2
ID	36	15	26
MT	22	14	18
NE	1	1	1
NM	1	1	1
NV	22	7	15
OK	3	4	4
OR	15	2	9
SD	4	1	3
TX	9	11	10
UT	64	50	57
WA	5	3	4
WY	33	29	31
Total	574	526	550

EXHIBIT 2: NUMBER OF RANGE LIVESTOCK EMPLOYERS			
State	2013	2014	Average
CO	21	22	22
ID	7	4	6
MT	7	22	15
ND	1	1	1
NM	1	1	1
NV	2	6	4
OK	0	1	1
OR	1	2	2
SD	3	4	4
TX	3	8	6
UT	18	29	24
WY	19	21	20
Total	83	121	102

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The Department disagrees with the comment that the proposed rule (or the Final Rule) should be considered a major rule requiring Congressional review under SBREFA. As detailed in the FRFA, the Department does not expect that the impact of the Final Rule will be over \$100 million annually, which is the monetary benchmark of significance for a rule to be classified as major under SBREFA. The Department also does not believe that the Final Rule, which was significantly modified from the NPRM in response to the comments, will result in a “major increase in costs or prices” for industries, governments, or consumers, or that it will have a “significant adverse effects” on the economy, such as on competition, employment, productivity or the ability to compete.

4. Subject-by-Subject Analysis

The Department’s analysis below considers the expected impacts of the following provisions of the Final Rule against the baseline (*i.e.*, the 2010 Final Rule; TEGL 32–10; and TEGL 15–06, Change 1): (a) Proportion/type of work permitted at the ranch (*i.e.*, not on the range); (b) the new methodology for determining the minimum monthly AEWR to be paid to workers; (c) H–2A application filing requirements; (d) job order submissions; (e) job order duration; (f) newspaper advertisements; (g) placement of workers on master applications; (h) employer-provided items; (i) meals; (j) potable water; (k) expanded cooking/cleaning facilities; (l) heating equipment; (m) recordkeeping; and (n) time to read and review the rule.

For each of these provisions, the Department discusses the relevant costs, benefits, and transfers. In addition, we provide a qualitative assessment of transfer payments associated with the increased wages and protections of U.S. workers. Transfer payments, as defined by OMB Circular A–4, are payments from one group to another that do not affect total resources available to society. Transfer payments are associated with a distributional effect but do not result in additional costs or benefits to society.

a. Proportion/Type of Work Permitted at the Ranch

The Final Rule codifies certain procedures for employers who apply to the Department to obtain temporary agricultural labor certifications to hire foreign workers to perform herding or the range production of livestock. The Final Rule also clarifies the proportion/type of work that is permitted to be performed by workers at the fixed-site

ranch. Any job duties performed at a place other than the range (*e.g.*, a fixed site farm or ranch) must be performed on no more than 50 percent of the workdays in a work contract period, and duties at the ranch must involve the production of livestock, which includes duties that are closely and directly related to herding and/or the production of livestock. The Final Rule thus clarifies and makes more specific the provision in current TEGL 32–10, which similarly provides that it applies in the unique situation of sheepherding, which requires “spending extended periods of time with grazing herds of sheep in isolated mountainous terrain,” and states that workers may perform “other farm or ranch chores related to the production and husbandry of sheep and/or goats on an incidental basis.” As in current TEGL 32–10, the Final Rule states that the work activities must also generally require the workers to be on call 24 hours per day, 7 days per week.

i. Costs

This change represents a cost to employers engaged in herding and range livestock production that have had or will have workers at the ranch for more than 50 percent of the contracted workdays or have had workers perform incidental duties at the ranch that are not closely and directly related to herding and/or the production of livestock. These employers will be excluded from applying for workers pursuant to the special procedures unless they commit to complying with the limitations for such workers in the future. The Department is not able to estimate this cost, however, because we do not know how many workers currently spend more than 50 percent of their days working at the farm or ranch, although we believe the number is very small given the commenters’ descriptions of the typical herding cycles, which generally involve months spent on the range. Particularly given the Final Rule’s revised definition of the term “range,” which no longer includes the word “open” and which deleted the NPRM’s proposed limitation to areas that were not fenced, we anticipate employers will be able to satisfy the requirement that at least 50 percent of the job order period be spent on the range. Further, the Final Rule deletes the NPRM’s proposed 20 percent cap on the percentage of ranch days that a worker could spend performing closely and directly related work. Therefore, the Department anticipates that it is likely that affected employers will make any necessary adjustments to their practices so that the duties performed by herding and range livestock workers at the

employer’s fixed-site ranch will be closely and directly related to herding and/or the production of livestock.

b. New Methodology for Determining the Wages of Workers

As discussed above, the Department received numerous comments related to the proposed methodology for determining worker wages. In particular, employers and their representatives commented on (1) perceived flaws with the Farm Labor Survey (FLS) data, (2) wages not accounting for herder benefits, (3) the effect the proposed wage increases would have on the profitability of operations, and (4) flaws in the reasoning behind the methodology. Worker advocates commented that the proposed wage methodology incorporated a weekly number of hours worked that was too low and that the transition period was inappropriate.

i. Use of FLS Data

Several commenters stated that it was inappropriate for the Department to determine proposed wages based on semi-annual FLS data produced by USDA’s National Agricultural Statistic Service (NASS). For the reasons set forth in the preamble, the Department is not using FLS data in the Final Rule, but rather is relying on the current FLSA minimum wage of \$7.25 as the starting point in the wage formula for 2016.

ii. Employee Benefits

Numerous employer commenters, including Mountain Plains and Western Range and Calvin Roberts, an individual employer, stated that the Department’s wage methodology was flawed because it did not account for the other “benefits” employees receive (*e.g.*, food, rent, clothes, and transportation). Mountain Plains and Western Range remarked that most H–2A herders are able to send all of their salary to their home country. Some commenters provided estimates pertaining to the amount of the benefits provided. Calvin Roberts estimated that the cost of housing, food, and owning and operating a car could range between \$1,200 and \$1,500 per month in western Colorado. Mountain Plains and Western Range estimated that the proposed wage increases would yield “actual wages” over \$2,000 per month using the methodology from the Colorado Wool Growers’ 2010 report. Andre Talbott-Soares, an individual employer, stated that California’s H–2A monthly wage of \$1,600 increases to at least \$2,100 once the costs of necessities (*e.g.*, food, housing, supplies, propane, travel, and I–94 visas) are included. Roswell Wool,

an individual employer, compared the net income of an H-2A worker making \$800 in net pay per month to a U.S. worker making \$16.50 per hour while working 40 hours per week. Once costs for rent, taxes, food, vehicle expenses, and clothing are taken into account, the commenter concluded that the H-2A worker would make more than such a U.S. worker in monthly net pay. Vermillion Ranch and Midland Livestock stated that meal credits should be included in the wage methodology in order to offset the substantial wage increase proposed by the Department.

The provision of these items does not suggest a different wage is appropriate. As discussed in the preamble, all H-2A employers are required to provide housing free of charge. Furthermore, all H-2A employers are required to provide the tools, supplies, and equipment necessary to perform the job free of charge as well as any job-related transportation. Moreover, sheep and goat herder employers are required under the existing TEGL to provide food free of charge, and livestock herder employers have been required to do so in recent years based on the SWA wage survey. Nonetheless, this economic impact analysis accounts for the cost associated with this requirement for livestock employers below in a separate section.

iii. Reasoning Behind Wage Methodology—U.S. Workers

The Utah Farm Bureau Federation and John and Carolyn Espil stated that the reasoning behind the wage methodology was flawed because the Department's attempt to protect U.S. workers by increasing wages is inappropriate. The commenters remarked that U.S. workers do not want to work in this occupation and are not suited for it. Mountain Plains and Western Range expressed the view that low wages are not the prime deterrent for workers and stated that, in their experience, despite higher wages in California they receive fewer U.S. applicants in sheep herding occupations in that state than in other states.

As discussed above, the Department has decided to set the monthly AEWR for these occupations based on a calculation of \$7.25 per hour multiplied

by 48 hours per week and adjusted annually for inflation. Because this Final Rule does not use the FLS-based AEWR to set the wage rates, the Department disagrees that meal credits should be included in the new wage formula to offset the wage increase because permitting food deductions under the wage methodology adopted in this Final Rule would erode much of the wage increase; therefore, it would not be sufficient address wage stagnation in these occupations.

As discussed in the preamble, we have elected not to use the FLS-based AEWR to set the monthly AEWR for these occupations because use of this wage source is likely to cause, rather than prevent, adverse effect on U.S. workers. For the reasons discussed above, this decision is not based upon flaws with the FLS as a data source or on commenters' views of the effects of the state law wage rate in California. As explained in the preamble, commenters' observations about California are inconsistent with DOL's experience that California is consistently among the states with the largest number of U.S. sheepherders identified in SWA surveys.

The Department also received many comments in response to the NPRM stating that costs related to the proposed wage increases were underestimated in the economic analysis. Mountain Plains and Western Range Association commented that the proposed wage requirements should be classified as costs rather than transfers. They reasoned that since most of the money earned by H-2A workers is spent in countries like Peru or Mexico, the proposed requirement results in a net loss for the U.S. economy. The Texas Sheep & Goat Raisers Association and Vermillion Ranch and Midland Ranch stated that the Department underestimated the costs of the proposed wage increases, especially for operations with more than three H-2A workers. The commenters estimated their annual costs using an estimate of \$13,860 per year for one worker based on the 5-year phase in. Vermillion Ranch, which has 18 workers, would expect to pay \$249,480 in additional wages, while Midland Ranch, which has 13 workers, would expect to pay \$180,180.

In contrast to the employer comments, the Workers Advocates' Joint Comment stated that the phase-in methodology to the new wage is not justified. They noted that the current wage rates already reflect stagnated wages and asked DOL to consider this history of stagnation in requiring the full FLS-based AEWR to be paid immediately. In the Final Rule the Department does decrease the transition period to two years, and we also increase the number of hours per week on which the monthly AEWR is based.

In the NPRM's EO 12866 analysis assessing the total costs and transfers to society, the proposed wage increases were classified as a transfer. Transfer payments are defined as monetary payments from one group to another that do not affect total resources available to society. However, contrary to the commenters' statements, the proposed wage increases also were classified as additional costs to small H-2A employers in IRFA assessing the impact to H-2A employers (as they are in the analysis in the Final Rule). Wage increases are both transfer payments (to society) and costs (to employers); however, we recognize that foreign employees send at least some of their wages to their families abroad.

The Final Rule changes the methodology for determining the required monthly AEWR for workers engaged in the herding or production of livestock on the range. The Final Rule sets the monthly AEWR for these occupations by multiplying a \$7.25 hourly wage rate by 48 hours per week, indexed annually beginning in the second year based on the ECI. The Final Rule uses a two-year transition period (at 80% and 90% of the full rate in 2016 and 2017, respectively) with full implementation in year three (2018).⁷¹ The Department analyzes the impact of this provision relative to the baseline—the 2015 herder monthly wage rates—which is the most recent AEWR data available and which reflects what employers currently are paying. To convert the monthly wage rate to an hourly wage rate, the Department divides the monthly wage rate by 48 hours and 4.333 weeks (which is derived from 52 weeks/12 months). Exhibit 3 presents the monthly baseline wages by state.

⁷¹ As explained in the FRFA, the Department considered three other alternatives to set the monthly wage rate: Using (1) the 1994 TEGL wage adjusted using the capped ECI approach and a three-year transition period with full

implementation in year four; (2) \$7.25 multiplied by a 44-hour estimated calculation of weekly hours and adjusted using the ECI beginning with the wages for year five, using a three-year transition period with full implementation in year four; and

(3) the FLS-based AEWR multiplied by a 65-hour estimate of weekly hours, implemented immediately and permitting a food deduction of the scope allowed under the regular H-2A program.

EXHIBIT 3: BASELINE WAGE—CY 2015 MONTHLY AEW			
State	Abbreviation	Current Required Wage for Sheep and Goat Herders	Current Required Wage for Range Livestock Production Workers
Alabama	AL	\$750.00	N/A
Arizona	AZ	\$750.00	N/A
Arkansas	AR	\$750.00	N/A
California	CA	\$1,600.34 ⁷²	N/A
Colorado	CO	\$750.00	\$875.00
Hawaii	HI	\$1,422.52 ⁷³	N/A
Idaho	ID	\$750.00	\$875.00
Missouri	MO	\$750.00	N/A
Montana	MT	\$750.00	\$875.00
Nebraska	NE	\$750.00	N/A
Nevada	NV	\$800.00	\$875.00
New Mexico	NM	\$750.00	\$875.00
North Dakota	ND	N/A	\$875.00
Oklahoma	OK	\$750.00	\$875.00
Oregon	OR	\$1603.33 ⁷⁴	\$1603.33
South Dakota	SD	\$750.00	\$875.00
Texas	TX	\$750.00	\$875.00
Utah	UT	\$750.00	\$875.00
Washington	WA	\$750.00	N/A
Wyoming	WY	\$750.00	\$875.00

Exhibit 4 presents the number and percentage of employers engaged in the herding or production of livestock on the range participating in the H-2A program and the state for which they applied for certified H-2A workers. The number of employers is based on the H-2A certification dataset over FY 2013–

2014. Note that each employer is counted once for each state for which the employer applied for workers, although due to the itinerant nature of the work, some employers applied for certification covering areas of employment for workers in multiple states. Hence, Exhibit 4 overstates the number of employers participating in

the H-2A herder and range livestock program. As Exhibit 4 illustrates, sheepherders and goat herders are most heavily concentrated in Arizona, California, Utah, and Colorado, while range livestock (*i.e.*, cattle) production workers are most heavily concentrated in Utah, Colorado, Wyoming, and Montana.

⁷² California's state-required sheep herder wage will increase to \$1777.98 on January 1, 2016, and employers in that state will be required to pay that increased wage on that date.

⁷³ Hawaii's monthly wage of \$1,422.52 is based on a 2012 prevailing wage survey conducted by California.

⁷⁴ This wage rate is annually adjusted by the CPI-U. The average percentage increase of the CPI-U in the past 3 years (2012–2014) was 1.54 percent. With the 1.54 percent increase per year, the forecasted monthly wage in Oregon in 2016 is \$1,628; \$1,653 in 2017; \$1,679 in 2018; \$1,705 in 2019; \$1,731 in 2020; and \$1,758 in 2021; \$1,785 in 2022 and

\$1,812 in 2023. The forecasted monthly wage with ECI-adjusted \$7.25 hourly wage is \$1,797 in 2025. Therefore, the monthly wage in Oregon is always expected to be higher than the forecasted monthly wage with ECI-adjusted \$7.25 hourly wage over the 10-year period, and, thus, no wage impact is expected for Oregon.

EXHIBIT 4: NUMBER AND PERCENTAGE OF H-2A EMPLOYERS BY OCCUPATION AND STATE				
State	Average Number of Sheep and Goat Herder Employers	Percent of Sheep and Goat Herder Employers	Average Number of Range Livestock Production Employers	Percent of Range Livestock Production Employers
AL	2	0.4%	-	-
AZ	167	30.3%	-	-
CA	151	27.6%	-	-
CO	50	9.1%	22	20.8%
HI	2	0.4%	-	-
ID	26	4.7%	6	5.7%
MT	18	3.3%	15	14.2%
ND	-	-	1	0.9%
NE	1	0.2%	-	-
NM	1	0.2%	1	0.9%
NV	15	2.6%	4	3.8%
OK	4	0.6%	1	0.9%
OR	9	1.6%	2	1.9%
SD	3	0.5%	4	3.8%
TX	10	1.8%	6	5.7%
UT	57	10.3%	24	22.6%
WA	4	0.7%	-	-
WY	31	5.7%	20	18.9%
Total	548	100.0%	106	100.0%

Note: Totals may not sum due to rounding. The total number of employers by state (654) exceeds the number of actual employers participating in the H-2A herder and range livestock program (485), as determined from a review of 2013 and 2014 applications for labor certification in the herding program. This discrepancy is because some employers (particularly sheepherding employers) submitted applications for certified H-2A workers in multiple states.

To estimate the new monthly AEWR, the Department first calculates the average quarterly wages and salaries ECI for each year from 2012 through 2014. We then take the average year-over-year growth rate and apply the resulting

value (2.0 percent) to the initial \$7.25 hourly base wage rate used in 2016 and do so each successive year to forecast the hourly base wage rates from 2017 to 2025. The new wage setting methodology will base the calculation

on 48 hours per week and includes a two-year transition period. The Department estimates the hourly base wage rate for each year of the analysis period as follows:

EXHIBIT 5: BASE WAGE RATE TRANSITION SCHEDULE FOR Final Rule	
Year	Base Wage Rate Estimate
2016	80 percent of \$7.25
2017	90 percent of the forecasted ECI-adjusted \$7.25
2018	100 percent of the forecasted ECI-adjusted \$7.25
2019	100 percent of the forecasted ECI-adjusted \$7.25
2020	100 percent of the forecasted ECI-adjusted \$7.25
2021	100 percent of the forecasted ECI-adjusted \$7.25
2022	100 percent of the forecasted ECI-adjusted \$7.25
2023	100 percent of the forecasted ECI-adjusted \$7.25
2024	100 percent of the forecasted ECI-adjusted \$7.25
2025	100 percent of the forecasted ECI-adjusted \$7.25

Exhibit 6 presents the forecasted ECI-adjusted \$7.25 hourly wage rates with the two-year transition period and full implementation in 2018.

EXHIBIT 6: FORECASTED ECI-ADJUSTED \$7.25 HOURLY WAGE WITH A TWO-YEAR TRANSITION PERIOD									
2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
\$5.80	\$6.65	\$7.54	\$7.69	\$7.84	\$7.99	\$8.15	\$8.31	\$8.47	\$8.64

To convert this to a monthly wage rate, the Department multiplies the above rates times the estimated 48 hours per week and by 4.333 weeks per month. Exhibit 7 presents the monthly wage rates.

EXHIBIT 7: FORECASTED MONTHLY ECI-ADJUSTED \$7.25 HOURLY WAGE WITH A TWO-YEAR TRANSITION PERIOD									
2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
\$1,206	\$1,383	\$1,568	\$1,599	\$1,631	\$1,662	\$1,695	\$1,728	\$1,762	\$1,797

Exhibits 8 and 9 present the wage differential between the monthly AEWR required under this Final Rule and the baseline by state for sheep and goat herders and range livestock production workers, respectively. In the case of California, the monthly AEWR wage is lower than the baseline wage for the first nine years, because state law requires a higher wage. In those years, the workers will continue to receive the baseline wage; therefore, no wage differential results. Similarly, Oregon's state required wage is higher than the

rate required under the AEWR calculation of this Final Rule, and it is adjusted annually for inflation using the CPI-U. Accordingly, workers in that state will continue to be paid the state-required rate and employers in Oregon will not be impacted by the wage increase in this Final Rule. Hawaii's current monthly wage of \$1,422.52 is based on a 2012 prevailing wage survey conducted by California, and the Final Rule's monthly AEWR is lower than Hawaii's current baseline wage in the first two years. The Department assumes

that the workers in Hawaii will continue to receive the baseline wage in those years; therefore, no wage differential results. Additionally, the hourly wage differentials for states that did not have a baseline wage because there were no H-2A workers employed as herders or range livestock workers are denoted as "N/A." Note that these values are for informational purposes only and were not used in the analysis.

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EXHIBIT 8: MONTHLY WAGE DIFFERENTIAL BY STATE FOR SHEEP AND GOAT HERDERS FOR FINAL RULE										
State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
AZ	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
AR	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
CA	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$19
CO	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
HI	\$0	\$0	\$146	\$177	\$208	\$239	\$273	\$306	\$339	\$374
ID	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
MO	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
MT	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
NE	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
NV	\$406	\$583	\$768	\$799	\$831	\$862	\$895	\$928	\$962	\$997
NM	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OK	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
OR	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
SD	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
TX	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
UT	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
WA	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047
WY	\$456	\$633	\$818	\$849	\$881	\$912	\$945	\$978	\$1,012	\$1,047

EXHIBIT 9: MONTHLY WAGE DIFFERENTIAL BY STATE FOR RANGE LIVESTOCK PRODUCTION WORKERS FOR FINAL RULE

State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AZ	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CO	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
HI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ID	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
MO	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MT	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
NE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NV	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
NM	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
ND	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
OK	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
OR	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
SD	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
TX	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
UT	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922
WA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
WY	\$331	\$508	\$693	\$724	\$756	\$787	\$820	\$853	\$887	\$922

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The Department multiplies the average increase in hourly wages per H-2A worker under this wage determination option in 2016 (\$1.53) by the estimate of weekly hours (48) and the average duration of need (50 weeks) to obtain the total increase per H-2A worker in 2016 (\$3,672). We then multiply the total increase per worker by the number of H-2A certified workers (2,481) to obtain total transfer due to increased wages of \$9.11 million

in 2016.⁷⁵ We repeat this calculation for

⁷⁵ This methodology may result in an overestimate. Using the number of H-2A workers certified may overestimate the number of affected workers because employers do not bring into the country all the workers for whom they are certified each year, and some workers are double counted because employers file multiple applications for certification to cover additional states and send the same workers to those states. In addition, some certifications are not for a full year, as some commenters indicate that they hire additional H-2A workers during peak seasons, such as the lambing season. Moreover, all workers do not stay for the entire period of the certification. Finally, as noted

each year of the analysis period, using the average increases in hourly wages.

in the preamble, some employer commenters stated that they already pay more than the TEGL-required wages, that they pay bonuses, or that they provide paid vacation. Nevertheless, there likely are some corresponding workers who would also receive the increased wages. The number of annual H-2A workers needed by employers may also be higher in future years. Therefore, the Department concludes that using the total number of workers certified and a 50-week average duration provides a reasonable estimate of the impact based on the available data.

This results in an average annual transfer payment of \$17.46 million.

The increase in the wage rates for some workers represents an important transfer from agricultural employers to corresponding U.S. workers, not just H-2A workers. As noted previously, the higher wages for workers associated with the Final Rule's methodology for determining the monthly AEWR will result in an improved ability on the part of workers and corresponding U.S. workers and their families to meet their costs of living and spend money in their local communities. On the other hand, higher wages represent an increase in costs of production from the perspective of employers that affects economic profit and creates a disincentive to hire H-2A and corresponding U.S. workers. The Department does not have sufficient information to measure the net effect of these countervailing impacts.

There also may be a transfer of costs from government entities to employers as a result of lower expenditures on unemployment insurance benefits claims. Unemployment insurance benefits replace a maximum of half of prior earnings in most states. However, to the extent that workers who had been laid off and were eligible for unemployment insurance benefits were not willing to accept a job at the current lower wage, and may now be willing to accept the job at the new higher wage, they would not need to seek new or continued unemployment insurance benefits. The Department, however, is not able to quantify these transfer payments.

c. Filing Requirements

The Final Rule permits an association of agricultural employers filing as a joint employer to submit a single job order and master *Application for Temporary Employment Certification* on behalf of its employer-members located in more than two contiguous states with different start dates of need.

This provision does not represent a change for an association filing a master application as a joint employer with its employer-members for sheepherding or goat herding positions. However, to ensure consistency in the handling of all employers eligible to use these procedures, the Final Rule extends this existing practice to employers in the range herding or production of other livestock.

i. Cost Reductions

This change represents a minor cost reduction to employers of H-2A workers in range livestock production occupations that file master applications as joint employers with their employer-

members. Due to data limitations regarding the time savings realized by filing a master application relative to separate applications and the extent to which range livestock production employers would file master applications as joint employers with their employer-members, however, the Department is not able to quantify this impact.

d. Job Order Submissions

The Final Rule extends the waiver of job order filing requirements in 20 CFR 655.121(a) through (d) to employers of H-2A workers in range livestock production occupations. A covered employer will submit its job order, *Agricultural and Food Processing Clearance Order*, Form ETA 790, directly to the National Processing Center (NPC), not to the State Workforce Agency (SWA). The employer will submit the job order to the NPC at the same time it submits its *Application for Temporary Employment Certification*, Form ETA 9142A, as outlined in 20 CFR 655.130.

This provision does not represent a change for an association filing a master application as joint employer with its employer-members for sheepherding or goat herding positions. However, to ensure consistency in the handling of all employers eligible to use these procedures, the Final Rule extends this existing practice to all employers involved in the range herding or production of other livestock.

i. Cost Reductions

This change represents a minor cost reduction to employers of H-2A workers in range livestock production occupations who will no longer be required to prepare and send a separate ETA Form 790 submission to the SWA and then communicate directly with the SWA about any concerns the SWA raises with the ETA Form 790. Due to data limitations, however, the Department is not able to quantify the staff time and resource costs saved relative to the baseline in which submission of the form and communication with the SWA is required.

e. Job Order Duration

The Final Rule requires that, where a single job order is approved for an association of agricultural employers filing as a joint employer on behalf of its employer-members with different start dates of need, each of the SWAs to which the job order was transmitted by the Contracting Officer (CO) or the SWA having jurisdiction over the location of the association must keep the job order

on its active file until 50 percent of the period of the work contract has elapsed for all employer-members identified on the job order, and must refer each qualified U.S. worker who applies (or on whose behalf an application is made) for the job opportunity. The Final Rule also requires that the Department keep the job order posted on the OFLC electronic job registry for the same period.

i. Cost Reductions

This change represents a possible cost reduction for an H-2A employer association that files a master application as a joint employer with its employer-members for workers in sheepherding and goat herding occupations. These employers were previously required to accept referrals throughout the work contract period. Under the Final Rule, these employers will only have to accept referrals for 50 percent of the work contract period, resulting in avoided costs of accepting referrals during the second half of the work contract period. Due to data limitations regarding the number of referrals during the second half of the work contract period, however, the Department is not able to quantify this impact.

f. Newspaper Advertisements

The Final Rule continues for sheepherding and goat herding occupations and expands to other range livestock production occupations the TEGL practice of granting a waiver of the requirement to place an advertisement on two separate days in a newspaper of general circulation serving the area of intended employment. Because both herding and the range production of livestock cover multiple areas of intended employment in remote, inaccessible areas within one or more states, the newspaper advertisement is impractical and ineffective for recruiting domestic workers for these types of job opportunities.

i. Cost Reductions

This change represents a cost reduction to employers of workers in range livestock production occupations. The Department estimates this cost reduction by multiplying the estimated number of applications filed by range livestock production employers each year (107, as determined from a review of 2013 and 2014 applications for labor certification in the herding program) by the average cost of placing a newspaper advertisement (\$258.64) and the number

of advertisements per employer (2).⁷⁶ We repeat this calculation for each remaining year of the analysis period. This results in an average annual cost reduction of \$55,349.

Because these activities require time on the part of a human resources manager on the ranch, we add to the result the incremental cost of preparing the advertisement, which we calculate by multiplying the estimated number of applications filed by range livestock production employers each year (107) by the time required to prepare a newspaper advertisement (0.5 hours), the hourly labor compensation rate of a human resources manager at an agricultural business (\$78.48), and the number of advertisements per employer (2).⁷⁷ This amounts to an average annual cost reduction of \$8,397.

In total, the cost reduction from not having to place the advertisement and saved labor yield an average annual cost reduction of \$0.06 million.

The Department received one comment pertaining to the cost reductions by waiving newspaper advertisements for workers in range livestock production occupations. The Department estimated a labor cost of a human resources (HR) manager to prepare the advertisement. Patrick O'Toole, a private citizen, stated that family members typically serve as the HR managers; hence, they do not receive benefits along with their wages, and they do not spend all of their time acting as the HR manager.

Even if family members serve as the HR managers and are not explicitly compensated for their time and work, it is still considered a cost reduction under the opportunity-cost approach used in the economic analysis for costing purposes. This is similar to the expenditure for family labor in the enterprise budget when family members are not actually paid for their labor. Thus, the Department believes that the inclusion of the labor cost of an HR manager is still reasonable.

g. Placement of Workers on Master Applications

The Final Rule requires that eligible U.S. workers who apply for the job

opportunities and are hired be placed at the locations nearest to them, absent a request for a different location by the U.S. workers. The Final Rule also requires that associations that fulfill the recruitment requirements for their members maintain a written recruitment report for each individual employer-member identified in the application or job order, including any approved modifications.

i. Cost Reductions and Costs

The U.S. worker placement requirement represents a minor cost reduction. Because U.S. workers will be placed at locations nearest to them, the Final Rule will yield a decrease in travel costs to arrive at and return from the work site. Due to data limitations regarding travel costs to arrive at and return from the work site for participating U.S. workers, however, the Department is not able to quantify this impact with any certainty.

The recruitment report requirement represents a cost to an association of employers of workers in range livestock occupations. Associations will be required to maintain a written recruitment report for each individual employer-member; however, associations are currently required to document all applications and their disposition, making this a change in the form of the recordkeeping rather than its substance. This will likely lead to a marginal increase in costs for the association to prepare and maintain a more disaggregated recruitment report for each employer-member named on a master application. The Department is not able to quantify this impact with any certainty, however, due to data limitations regarding the time required for associations to prepare and maintain a more disaggregated recruitment report.

h. Employer-Provided Items

In the NPRM, the Department proposed to require that the job offer specify that the employer will provide, without charge or deposit charge, those tools, supplies, and equipment required by law, by the employer, or by the nature of the work to do the job safely and effectively. Because of the isolated nature of these occupations, an effective means of communication between worker and employer—to enable the employer to check the worker's status and the worker to communicate an emergency to persons capable of responding—is required because it is necessary to perform the job safely and effectively. The workers' location may be so remote that electronic communication devices may not work at

all times. Therefore, the NPRM proposed to continue the TEGLS' current requirement for the employer to provide an effective means of communicating in an emergency. The Final Rule similarly provides that where the employer will not otherwise make regular contact with the worker (*e.g.*, when delivering food or checking on the worker and herd in-person), the employer must make arrangements so that the workers will be geographically located in a place where the electronic communication device will function on a regular basis (*e.g.*, mobile phone in an area with adequate reception) so that the workers' safety and needs can be monitored. The employer must include in the job order a simple statement identifying the type of electronic communication device that it will provide and the frequency with which it will make contact with the workers when the devices may not operate effectively.

The Department received several comments on the cost of employer-provided items—including the cost of maintaining regular contact. Sharon O'Toole, an individual employer, stated that it is not necessary to quantify the cost of regular contact between employers and herders, as it has been a common practice for decades to ensure the conditions of herders, sheep, horses, and dogs, which is in an employer's business interest. Contact usually occurs when someone delivers items such as food and water. In contrast, the Wyoming Farm Bureau Federation stated that it is not possible to get a cellular signal in some areas. The commenter noted that a satellite phone plan that allows 10 minutes of usage per month costs at least \$300 per year, not including the price of the phone, and that plans can cost as much as \$2,000 per year.

The Department understands that there is a range of different ways to establish effective communication between employers and their workers to address the workers' basic needs and to enable contact in an emergency. Employers are not required to provide satellite phones, as they do not always provide reliable service, when other effective means of communication are available. The Department expects that very few employers will have to purchase satellite phone to communicate with their workers.

The Department also received several comments pertaining to the quantification and data sources for other items they stated should be monetized in the economic analysis. For example, Governor Matthew H. Mead of the State of Wyoming remarked that the

⁷⁶ This newspaper advertisement cost estimate is based on an advertisement of 158 words placed in *The Salt Lake Tribune* for one day (Source: *The Salt Lake Tribune*. Available at <http://placead.yourutahclassifieds.com/webbase/en/std/jsp/WebBaseMain.do>. Accessed Nov. 13, 2014).

⁷⁷ The Department estimates that this work would be performed by a human resources manager at an agricultural employer at an hourly rate of \$54.88 (as published by the Department's OES Survey, O*Net Online), which we multiply by 1.43 to account for employee benefits to obtain a total hourly labor cost of \$78.48.

economic analysis did not reflect an analysis of the complete compensation structure. Several commenters similarly commented on the cost of providing items to H-2A workers that, in the commenters' view, supplement the workers' wages. For example, FIM Corp. stated that the cost of "benefits" (listing for example housing, utilities, food, satellite TV, cell phone service, laundry, workers' compensation insurance, supplies, travel to and from the home country, administrative costs for Western Range Service, and banking services) for each shepherd is at least \$1,220 per month beyond the wages paid, bringing the total compensation to over \$2,000 per month. Donald Watson expressed that the cost of workers' compensation insurance, housing, provisions, and incidental herding costs nearly double the annual cost per herder from \$10,000 to \$20,000. Raymond Talbott, an individual employer, stated that although H-2A wage is \$1,600 per month in California, when the cost of items such as commissary, housing, supplies, propane, travel, and I-94 visas are included, the wage increases to at least \$2,100.

Many of these costs, such as the cost of housing and related provisions (utilities/propane), are required by the H-2A program generally; thus those costs are not new or unique under this Final Rule. Other employer business expenses, such as a worker's travel to and from the home country, visa fees, or employer association fees, also are the responsibility of the employer under the standard H-2A regulations. Anything that is newly required by this Final Rule, such as free meals for range livestock workers, is acknowledged and discussed separately.

Finally, many commenters, including Mountain Plains and Western Range, the Washington State Sheep Producers, and John and Carolyn Espil, stated that the Department should monetize the impact caused by the change in the definition of "open range," which they asserted would exclude approximately 40 percent of employers that currently use the H-2A program. As explained in detail in the preamble, commenters explained that livestock grazing varies substantially, depending on the particular ranch owner and/or the geographic location, and they emphasized that modern grazing contains fencing. Commenters almost unanimously opposed using fencing as a defining factor for "open range." In response to the comments related to definition of "open range," the Department decided to use a modified version of the FLSA definition of "range" to provide flexibility and

account for the changes in herding practices over time. The Department believes this revised definition of "range" will not impose any additional costs on employers, as most comments indicate that employers assign their H-2A workers to the range for at least the majority of the year.

In the final rule, employers are also required to provide:

- Containers appropriate for storing and using potable water and, in locations subject to freezing temperatures, containers must be small enough to allow storage in the housing unit to prevent freezing;
- facilities, including shovels, for effective disposal of excreta and liquid waste in accordance with the requirements of the state health authority or involved Federal agency; and
- appropriate materials, including sprays, and sealed containers for food storage, to aid housing occupants in combating insects, rodents and other vermin.

i. Costs

The requirement that employers arrange for the workers to be located in a place where the electronic communication device will operate effectively on a regular basis when they are stationed in areas where the devices may not work, or to provide regular in-person contact, represents a possible minor cost to herding or range livestock production employers. This may impose restrictions on land use or require the purchase of particular types of communication devices. The Department cannot, however, predict this impact or quantify it as a cost to employers, but we anticipate that it will be minimal as the current TEGLs contain a similar communication requirement and many employer commenters stated that they are in routine contact with their workers to monitor their health and well-being and that of the herd.

The Department believes that most existing employers already provide to H-2A workers on the range containers for storing and using potable water, shovels for effective disposal of excreta and liquid waste, and insect and rodent control materials such as sprays and sealed containers for food storage in order to satisfy their current requirements under the TEGLs. Even for the small fraction of employers who currently do not provide any such items to H-2A workers on the range, the additional costs would be trivial, at most \$50 in 2016.

i. Meals

All H-2A employers must provide either three meals a day or free and convenient kitchen facilities. Currently, as required under the sheepherding and goat herding TEGL and pursuant to practice in the industry for range production of livestock occupations, employers with these range herding occupations must provide food, free of charge, to their workers. The Final Rule adopts this common practice as a requirement for employers engaged in the range production of livestock (who now must provide free food pursuant to the prevailing industry practice) and continues it for employers engaged in sheep or goat herding. The Final Rule also requires employers to disclose it in the job offer. The Final Rule clarifies that the food must be "sufficient" and "adequate" and that it must include a daily source of protein, vitamins and minerals. The employer commenters agreed that the physical demands of the job require a protein-rich diet, and that the workers need and deserve good, nourishing food; they stated that they currently provide such food to their workers, typically in response to the workers' expressed preferences for particular food.

i. Costs

Because this is a current requirement of the sheepherding and goat herding TEGL, this provision does not represent a cost to sheepherding and goat herding employers (the Department concludes that the clarifications requiring that the food be sufficient and adequate, and include a daily source of protein, vitamins and minerals, impose no additional quantifiable cost, particularly given the employers' assertions that they are providing such food now). This provision does, however, represent a cost to other range livestock production employers.⁷⁸ The Department estimates this cost by multiplying the number of days workers receive meals on a weekly basis (7), the average cost of three meals per day (\$11.86), and the average duration of need (50 weeks) to obtain the total cost of meals per worker (\$4,151).⁷⁹ We then multiply the total cost of meals per worker by the estimated number of range livestock

⁷⁸ Since 2013 livestock employers have been required to provide food free of charge because payment of food is included in the wage rate identified in the SWA surveys. Therefore, the cost estimate for this provision is an overestimate.

⁷⁹ The daily meal cost estimate of \$11.86 is from *Allowable Meal Charges and Reimbursements for Daily Subsistence* published by the U.S. Department of Labor, Employment & Training Administration (Source: http://www.foreignlaborcert.doleta.gov/meal_travel_subsistence.cfm. Accessed July 30, 2015).

production employers in 2016 (102) and the average number of H-2A workers per employer needing meals on a weekly basis (4.2) to obtain an average annual cost of \$ 1.78 million.⁸⁰

In addition to the cost incurred to purchase food, these range livestock production employers would incur costs to transport the food to the workers. The Department assumes that food would be transported to the workers on a weekly basis along with the potable water. The costs related to transporting food and potable water are accounted for below in the section on costs related to potable water.

The Department received only a handful of comments directly pertaining to the economic analysis of providing meals without charge to workers. However, as discussed in the preamble, some commenters opposed the proposed provision to provide daily meals to workers for free and wanted to be permitted to take a wage credit for the cost of meals, while others thought that providing free food was appropriate. For example, Sharon O'Toole stated that if an employer is not already providing adequate food to employees, then they are in violation of other laws and should not be covered by this rule. She also commented that providing access to expanded cooking facilities is unnecessary because the workers are already provided with hot meals at the ranch.

Vermillion Ranch and Midland Ranch stated that the cost of providing meals increases operating costs substantially when the number of workers hired increases. They said that for Vermillion Ranch, the cost of the meal provision requirement would be \$72,954 for 18 workers as opposed to the \$12,159 estimated by the Department. The Siddoway Sheep Company stated that during the winter lambing season it

employs a cook who prepares the workers three meals each day, and that when workers are on the range, it purchases food every eight to 10 days. The commenter expressed that actual food expenditures, including meat grown on the ranch, average \$476 per worker per month. Siddoway provided three alternatives that it supported: (1) Allowing employers to deduct the cost of purchasing the food products on the employee's grocery list; (2) a ranch-specific deduction based on annualized expenditures over a three-year period; and (3) an industry-wide deduction equal to 128 percent of the liberal USDA Food Plan Cost, which is what it estimated it spends on meals. ASI and Public Lands Council, and Mountain Plains and Western Range, also pointed to the USDA liberal meal plan and stated that such a meal plan is more expensive than the subsistence meal charges that the Department uses for workers. For the reasons discussed in the preamble, including the current free food requirements and that the Final Rule uses the FLSA minimum wage rate of \$7.25 as the starting point for the wage requirement, we did not permit employers to offset the cost of meals to avoid continued wage stagnation; rather, we have identified it as a cost for range livestock production employers.

j. Potable Water

The Department received several comments related to the costs of transporting meals and potable water to workers. As summarized below, the commenters (1) stated that the economic analysis did not fully capture the cost, (2) described the amount of water provided and the types of containers typically used at their locations, (3) listed alternative sources of water not specified by the Department, and (4) were generally opposed to employers being required to provide water for laundry.

Several commenters remarked that the Department's economic analysis underestimated the cost to transport meals and potable water; several commenters also provided cost estimates. Eph Jensen Livestock, LLC and Mountain Plains and Western Range stated that the Department did not account for the actual distances traveled between the ranch and camp or how the time needed to travel can vary depending on the type of terrain. Eph Jensen Livestock, LLC, stated that the Department did not account for areas in which vehicle travel is prohibited or impossible. The Wyoming Farm Bureau Federation also commented on the difficulties associated with using a trailer for water. The trailers must often

be driven on roads that are two tracks or not maintained. These conditions make it difficult to drive in reverse and drivers occasionally get stuck. In addition, workers' mobile housing units already have a trailer attached. Attaching another trailer would make traveling unsafe, increase traveling time, and result in additional costs. The commenter also noted that some states prohibit the use of triple trailers.

Mountain Plains and Western Range and Sharon O-Toole stated that the estimated costs for providing meals and water did not include the cost of purchasing additional trucks or water trailers. Several commenters stated that in addition to the costs for the truck and trailer, the Department should include the cost to hire a driver with a commercial driver's license. They noted that it recently cost them \$45,000 for a cab with 500,000 miles and \$8,000 for a used trailer. Sims Sheep Co. LLC stated that trailers and tanks would be more expensive than estimated because they would need to be tailor-made to withstand the weight of the water and poor road/terrain conditions. Paul Nelson stated that it costs \$15 for gas each trip, \$30 per worker to transport water and other necessities. Cindy Siddoway stated that transportation to mountain camps would require them to purchase eight pack horses, which would cost \$9,600 in addition to food and pack saddles. Vermillion Ranch and Midland Ranch stated that the costs of providing sufficient potable water for drinking, cleaning, and laundry using the Department's estimate of \$4,910.96 per worker would be \$88,397.28 per year and \$63,842.28 per year for Vermillion Ranch and Midland Ranch, respectively, given their large number of employees.

Paul Nelson and Cindy Siddoway stated they provide water in five-gallon containers. Donald Watson stated that he provides water in either five-gallon containers, 50-gallon barrels, 400-gallon tanks, or from containers filled by hose, depending on the location. A handful of individual employers warned that large water tanks could restrict workers' access to water during winter months if the water freezes, and that a preferable alternative would be smaller potable water containers that could fit inside the workers' housing units and would thus not be subject to freezing.

Several commenters listed alternative sources of water. The Wyoming Farm Bureau Federation and Sharon O'Toole listed melted snow as an alternative water source, and Cindy Siddoway listed mountain springs and streams as alternative sources. Commenters stated that workers have tools to boil water to

⁸⁰ The FY 2013 and FY 2014 certification data show an annual average of 954 applications certified for an average of 2,482 workers in the herding and range production of livestock program, or 2.6 workers per application. The Department concluded that this could be an underestimate because some employers file multiple applications per year. Therefore, we also attempted to identify the number of unique employers filing applications. We estimate that an annual average of 485 unique employers filed applications, which would indicate more than five workers per employer. However, the Department concluded that this could be an overestimate because employers do not bring into the country all the workers for which they are certified each year. Furthermore, some employers file multiple applications because their itinerary changes and they need to reapply to receive authorization to send workers to another state, even though they will be the same workers. Therefore, we assumed an average of 4.2 workers per employer, which is consistent with the estimate from the Mountain Plains 2015 telephone survey of its members discussed by the SBA Office of Advocacy.

make it potable, and some commented that their workers have not gotten sick drinking from these alternative sources and that workers rarely use purification methods such as water filters or purification tablets that have been made available by the employer.

The Department understands that these alternative sources of water would be almost costless relative to the estimated costs of potable water in the economic analysis. However, such alternative sources are not always available, and for health reasons the Department must require that workers have available potable water (or in exigent circumstances the means to make water potable) for consumption, cooking, and dishwashing.

Several commenters opposed the proposed requirement for employers to provide enough water for laundry, stating either that non-potable water sources are often available that are adequate for washing laundry or, more often, that they wash laundry for the workers and deliver it when they bring food to the workers. They stated that this is more cost-effective than transporting water for workers to wash laundry themselves.

A few commenters stated how much water was typically needed in their operations. Sharon O'Toole stated that 40 gallons of potable water per week is enough for a worker to drink and wash. Eph Jensen Livestock, LLC commented that the amount of water needed varies depending on climate.

The Workers Advocates' Joint Comment outlined several suggestions regarding what constitutes an adequate supply of potable water. They stated that the supply of water should be defined as 4 to 4.5 gallons of potable water per day in clean and sealed containers, which amounts to 28 to 31.5 gallons per week. They also noted that the water supply should include an additional 50 gallons per week for cleaning, bathing, and laundry, which is based on comments from range workers. The commenters stated that range workers should be supplied with a means for water purification only in exigent circumstances (e.g., forest fires), and that the Department should clarify that the supply of water is "for workers only" and not for the sheep dogs or horses. In the NPRM the Department assumed that each worker required 28 gallons of potable water per week. Several commenters stated that this was not a sufficient amount and suggested the Department use an estimate based on 4 to 4.5 gallons of potable water per day in clean and sealed containers.

For the reasons discussed in the preamble, in the Final Rule the

Department requires employers to provide at least 4.5 gallons of potable water per day, which amounts to at least 31.5 gallons of potable water per worker per week (4.5 x 7). The Department does not specifically define the minimum quantity of water that must be provided for bathing and laundry. The Final Rule also allows the use of alternate sources of water for bathing and laundry where such sources are readily available. Moreover, we note that if employers provide laundry services for workers that likely will substantially minimize their need for water for that purpose. Finally, the Final Rule allows the employer to request a variance from the requirement to provide 4.5 gallons of potable water when workers are located in areas that are not accessible by motorized vehicle; the employer must identify an alternative water supply and disseminate both the means and methods for testing and making potable the water obtained for drinking and cooking from such alternative supplies.

i. Costs

In the NPRM's EO 12866 analysis, the Department estimated that range sheep, goat, and other livestock production employers already must incur the cost under the TEGs of transporting both food and water for cooking, consumption and bathing to their workers on the range, which must meet state health authority standards. The NPRM proposed to add a requirement for additional water for cleaning and laundry. The Department assumed that the additional water would be transported to the workers on a weekly basis along with the previously required food and potable water. The cost of providing a water supply to workers was estimated as the sum of the cost of the water itself, the cost of purchasing utility trailers to transport the additional water and meals, the cost of mileage for those vehicles, and the wages for the drivers to transport the additional water and meals. The Department noted that because employers are currently required to provide food and water to workers, our cost estimate in the analysis likely was an overestimate.

The Final Rule continues the same general approach, with the modifications discussed above. The Department concludes, given the changes made in the Final Rule, particularly the employers' ability to identify alternative sources of water for bathing and laundry, that the NPRM's general approach remains valid. In addition, because the Final Rule requires only that workers spend the majority of their time on the range, we continue to believe that the estimate

likely produces an overestimate because the analysis assumes that the water and food is transported 50 weeks of the year.

The Department estimates the cost of purchasing the water by multiplying the estimated number of employers in each year (485) by the average number of H-2A workers per employer needing potable water on a weekly basis (4.2), the number of gallons of potable water needed per worker on a weekly basis (31.5), the average cost of a gallon of potable water (\$0.005), and the average duration of need (50 weeks).⁸¹ This results in an average annual cost of \$16,041.

Because the employers must have the means to transport the potable water and food to the workers, the Department estimates the cost of purchasing utility trailers. We assume that 10 percent of agricultural employers do not currently have a trailer sufficient to transport the additional water and food to workers. In the first year of the rule, we include the cost incurred by existing and new H-2A employers to purchase trailers; in future years, we include the cost incurred only by new participants. To calculate the cost for the first year of the Final Rule, we multiply the total number of participants in the program (485) by the assumed percentage of employers that would need to purchase a trailer (10 percent). We then multiply the number of employers needing to purchase a trailer (49) by the average cost of a trailer (\$839.34) to estimate the total cost of purchasing utility trailer each year (\$40,708).⁸² To calculate the cost for each of the remaining years, we estimate the average number of employers joining the program that would need to purchase a trailer each year, which we calculate by multiplying the number of participants joining the H-2A program (49) by the assumed percentage of employers that would need to purchase a trailer (10%).⁸³ We

⁸¹ This potable water cost estimate is from the 2014 *Water and Wastewater Survey* produced by the Texas Municipal League (Source: <http://www.tml.org/surveys>. Accessed Nov. 13, 2014). It is estimated based on the average cost of potable water for commercial entities in Texas cities with a population below 2,000 and based on the fee for 50,000 gallons.

⁸² This trailer cost estimate is based on the average costs for a 5 x 8 ft. utility trailer from Tractor Supply Co. (Source: <http://www.tractorsupply.com/en/store/search/utility-trailers>. Accessed Nov. 13, 2014), Lowes, and Home Depot. Given the changes in the Final Rule, particularly the employers' ability to identify alternative sources of water for bathing and laundry, we conclude it is not necessary to assume a cost for a water truck as a few commenters suggested.

⁸³ Based upon H-2A program data, the Department assumes that, due to turnover, 10% of the average number of employers that participate in

then multiply the number of employers joining the H-2A program needing to purchase a trailer (5) by the average cost of a trailer (\$839.34) to estimate the total cost of purchasing utility trailers in each remaining year (\$4,071).

The Department also estimates the cost of mileage on the employers' vehicles. The mileage reimbursement rate is intended to cover the costs of operating a vehicle for business purposes. The costs encompassed by the standard mileage rate are standard maintenance, repairs, taxes, gas, insurance, and registration fees. Essentially, the standard mileage rate is intended to cover the expenses that an individual would report if using the actual car expenses deduction. While the standard mileage reimbursement rate is simply an estimate and may end up being more or less than actual car expenses, it reflects the full cost of operating a truck for transporting the water and meals. However, the Department assumed that employers already would have a truck for delivering food and water as it is currently required by TEG and therefore, did not include the cost of purchasing a new truck in this analysis. We estimate this cost by multiplying the estimated number of employers in each year (485) by the average cost per mile of owning and operating an automobile (\$0.58), the number of miles driven (roundtrip) to deliver the water and meals (100), and the number of roundtrips expected per year (50).⁸⁴ This calculation results in an average annual cost of \$1.4 million.

Because these activities require time on the part of an agricultural worker on the ranch, the Department estimates the cost of transporting the potable water and food to the workers, which we calculate by multiplying the estimated number of employers in each year (485)

the H-2A program each year (485) join the H-2A program each year, which results in 49 new employers per year.

⁸⁴ This cost per mile of owning and operating an automobile is based on the average costs in the DOT Bureau of Transportation Statistics. (source: http://www.rita.dot.gov/bts/sites/rita.dot.gov/bts/files/publications/national_transportation_statistics/html/table_03_17.html Accessed July 30, 2015), which cites the costs presented by American Automobile Association Exchange (Source: <http://exchange.aaa.com/automobiles-travel/automobiles/driving-costs/> Accessed July 30, 2015). The Department assumes the workers are all located within the 100-mile roundtrip distance so only one roundtrip per employer per week would be needed to transport water and meals to workers. Although the Department received a handful of general comments stating that we had underestimated the distances involved and the time required, they did not provide data or alternative estimates of their actual distances or time spent. Therefore, the Department has not modified its assumptions.

by the assumed time required to transport the potable water and food (2.86 hours), the hourly labor compensation rate of an agricultural worker (\$13.40), and the number of roundtrips per year (50).⁸⁵ This calculation results in an average annual cost of \$0.9 million. As mentioned above, this may be an overestimate as the Final Rule only requires that workers be on the range for the majority of workdays in the job order period.

This calculation yields an average annual cost of \$2.4 million for the cost of the water, utility trailers, vehicle mileage, and labor to deliver the additional water and food.

k. Expanded Cooking/Cleaning Facilities

The Department recognizes that there are times when workers are located at or near the ranch or farm (or a similar central location) for certain operations that are a normal part of the herding cycle, such as birthing (in some cases), shearing, or branding. In such instances, the Final Rule allows workers to continue to use their mobile housing, which may be preferred by workers, even where access to fixed housing exists. However, the Final Rule requires (as the NPRM proposed) in such a situation that workers be granted access to facilities, including toilets and showers with hot and cold water under pressure, as well as cooking and cleaning facilities that satisfy the standard housing requirements if the employer does not provide meals.

The Department received a couple of comments in response to the NPRM pertaining to the cost to provide expanded cooking facilities at a ranch or farm. Sharon O'Toole commented that providing access to expanded cooking facilities is unnecessary because the workers are already provided with hot meals at the ranch. Vermillion Ranch and Midland Ranch objected to the term "ranch" in conjunction with the proposed locations of the expanded cooking facilities.

i. Costs

As the Department stated in its NPRM economic analysis, we do not expect

⁸⁵ The Department assumes that the water delivery will be performed by an agricultural worker at an hourly rate of \$9.37 (as published by the Department's OES Survey, O*Net Online), which we multiply by 1.43 to account for employee benefits to obtain a total hourly labor cost of \$13.40. The time required to transport the potable water and meals roundtrip was estimated using the assumptions that a roundtrip is 100 miles and that the agricultural worker would drive at 35 mph. The Department assumes the workers are all located within the 100-mile roundtrip distance, so only one roundtrip per employer per week would be needed to transport water and meals to workers.

any additional costs for construction or expansion of cooking facilities because existing farm kitchens will be able to increase production to a sufficient extent to provide for the additional workers. As several commenters stated, some employers already provide hot meals to H-2A workers at the ranch. Alternatively, employers need not incur any additional cost to construct or expand cooking facilities as they could simply provide the workers with access to the existing farm kitchen to prepare their own meals.

The requirement to provide access to facilities such as toilets and showers with hot and cold water under pressure, however, will likely impose a cost on herding and range livestock production employers that do not have such facilities for worker use. To estimate the cost of constructing or expanding the cleaning facilities for the first year of the Final Rule, the Department estimates the number of existing H-2A participants that would need to construct/expand cleaning facilities, which we calculate by multiplying the number of existing H-2A participants (485) by the assumed percentage of employers that would need to construct or expand their facilities (20%). We then multiply the number of existing employers that would need to construct/expand facilities (97) by the average cost per square foot to construct or expand cleaning facilities (\$270.00) and the assumed size of the cleaning facility (150 sq. ft.).⁸⁶ This calculation results in a cost of \$3.93 million in 2016.

To calculate the cost for each of the remaining years of the Final Rule, we estimate the average number of employers joining the program that would need to construct such facilities, which we calculate by multiplying the number of participants joining the H-2A program (49) by the assumed percentage of employers that would need to construct or expand their facilities (20%). We then multiply the number of employers joining the H-2A program needing to construct or expand their facilities (10) by the average cost per square foot to construct or expand cleaning facilities (\$270.00) and the assumed size of the cleaning facility (150 sq. ft.) to estimate the total cost of constructing or expanding facilities in each remaining year (\$0.4 million). Over the 10-year period, this calculation yields an average annual cost of \$.75 million to existing and new employers.

⁸⁶ This cost per square foot estimate is based on the average cost to add a bathroom to a building from The Nest (Source: <http://budgeting.thenest.com/average-cost-per-square-foot-add-addition-house-23356.html>. Accessed Nov. 13, 2014).

I. Heating Equipment

In the Final Rule, as specified in § 655.235, the mobile housing unit provided to workers must include operable heating equipment that supplies adequate heat for workers in locations where required for the health and safety of the workers by the climate. Where the climate in which the housing will be used is mild and the low temperature for any day in the work contract period is not reasonably expected to drop below 50 degrees Fahrenheit, no separate heating equipment is required as long as proper protective clothing and bedding are made available, free of charge or deposit charge, to the workers.

i. Costs

The Department acknowledges that this may impose a cost on some employers, but we do not have sufficiently accurate location and temperature available to identify how many workers may require such additional heating units or how many of the mobile housing units already contain built-in heating equipment. The Department evaluated possible portable heating equipment units that are suitable for a housing unit of approximately 150 square feet to determine the range of costs required to purchase heating units. We found 12 different types of portable heating equipment suitable for heating at least 150 square feet, including propane units, kerosene units, and electric units. The propane units range in cost from approximately \$69 to \$280;⁸⁷ the kerosene units range in cost from approximately \$119 to \$188;⁸⁸ and the electric units range from approximately \$147 to \$218.⁸⁹

The Department estimates the number of existing H-2A participants that would need to purchase portable

heating equipment, which we calculate by multiplying the number of existing H-2A participants (485) by the assumed percentage of employers that would need to purchase portable heating equipment (20%). We then multiply the number of existing employers that would need to purchase portable heating equipment (97) by the average cost of a portable propane heating unit (\$150.00). This calculation results in a cost of \$14,550 in 2016. The Department added gas costs to employers by assuming that the average price of propane is \$3 per gallon and that it would require approximately 323 gallons⁹⁰ of propane to adequately supply heat for workers in locations where the temperature is expected to drop below 50 degrees Fahrenheit. This calculation results in a cost of \$93,993 per year.⁹¹ The total cost of providing portable heating equipment and propane is \$108,543 in 2016.⁹²

To calculate the cost for each of the remaining years of the Final Rule, we estimate the average number of employers joining the program that would need to purchase such equipment, which we calculate by multiplying the number of participants joining the H-2A program (49) by the assumed percentage of employers that would need to purchase portable heating equipment (20%). We then multiply the number of employers joining the H-2A program needing to purchase such equipment (10) by the average purchase cost (\$150.00) to estimate the total cost of purchasing portable heating equipment in each remaining year (\$1,455). The total cost of providing portable heating equipment and propane is \$95,448 in 2017 and thereafter.⁹³ Over the 10-year period, this calculation yields an average annual cost of \$96,758 to existing and new employers for purchasing the equipment and propane.

m. Recordkeeping

The NPRM required that employers generate a daily record of the site of the employee's work, whether it was on the range or on the ranch or farm, and for periods when the worker was on the ranch a record of the hours worked and duties performed. The Department received several comments on the costs of generating daily records of a worker's hours and duties in response to this requirement. Several commenters stated that the Department underestimated the

costs associated with the proposed requirement, while one commenter stated that the Department overestimated the costs.

For example, the Wyoming Farm Bureau Federation and Sims Sheep Co. LLC commented that the Department underestimated the costs. The Wyoming Farm Bureau stated that the Department used flawed assumptions in its estimation and remarked, along with John and Carolyn Espil, that most employers do not have an HR manager—often family members are used to perform these tasks. Secondly, the commenter stated that ranch operations do not occur in locations such as offices or manufacturing facilities that are convenient for record keeping. Without access to a clock, it is difficult to track the amount of time spent on activities, which may change unexpectedly (e.g., if an animal gets sick and its care must be immediately prioritized). Thirdly, the commenter stated the proposed requirement would require a clerk as herders do not have the necessary skills. Finally, additional costs would be required for an employer to transfer the employees' records onto a time sheet for the Department's records. The Wyoming Farm Bureau concluded that the benefits do not outweigh the costs.

The Worker Advocates' Joint Comment stated that the Department's methodology for estimating the cost of complying with the proposed record keeping requirement was reasonable; however, they stated the cost may have been overestimated. The commenter noted that operations that employ workers who are not covered by the current herder exemptions are already required to have payroll systems that meet Fair Labor Standards Act (FLSA) requirements, and that it would not require much time to incorporate herder information into those systems. The commenter stated that the benefit of having these records available for monitoring and enforcement outweigh the minor cost of compliance, as the employees generally would bear the responsibility for recording their own time.

The Final Rule modifies the NPRM's proposed recordkeeping requirements by eliminating the requirement to record hours worked when workers are not on the range and by eliminating the requirement to record the duties performed each day when workers are not on the range. The Final Rule retains only the requirement to record daily whether work was performed on the range or at the farm or ranch.

⁸⁷ <http://www.grainger.com/product/DAYTON-Portable-Gas-Heater-12H991>; <http://www.homedepot.com/p/Dyna-Glo-15k-25k-BTU-Propane-Convection-Heater-RMC-LPC25DG/202223055>; <http://www.grainger.com/product/DAYTON-Tank-Top-Portable-Gas-Heater-WP105137>; <http://www.grainger.com/product/DAYTON-Convection-Portable-Gas-Heater-WP105135> (Accessed 07/27/15).

⁸⁸ <http://www.homedepot.com/p/DuraHeat-23-000-BTU-Kerosene-Portable-Heater-DH2304/100045793>; <http://www.homedepot.com/p/Unbranded-Duraheat-Compact-Convection-Heater-DH1051/202221099>; <http://www.grainger.com/product/SENGOKU-Omni-Radiant-4NHH2>; <http://www.grainger.com/product/SENGOKU-Radiant-Convection-Heater-5UDU3> (Accessed 07/27/15).

⁸⁹ <http://www.grainger.com/product/PRO-TEMP-Portable-Heater-32MY65>; <http://www.grainger.com/category/hvac-and-refrigeration/catalog/N-k00>; <http://www.grainger.com/product/DAYTON-Electric-Space-Htr-3VU34>; <http://www.grainger.com/product/PRO-TEMP-Portable-Heater-32MY66> (Accessed 07/27/15).

⁹⁰ 323 = 4 months × 4.333 weeks × 7 days × 8 hours + 3 hours (average heating time per gallon of propane for a portable gas heater with 3,000 BTU).

⁹¹ \$93,993 = \$3 × 97 × 323.

⁹² \$108,403 = \$14,550 + \$93,993.

⁹³ \$95,448 = \$93,993 + \$1,455.

i. Costs

This change represents a minor cost to herding or range livestock production employers who are not already creating and retaining records. Given that the Department received contradictory comments that it had either overestimated or underestimated the costs of the proposed recordkeeping requirement, the Department maintains its average estimate of the time required. The Department estimates the cost by multiplying the time required to prepare and store the records by the average compensation of a human resources manager at an agricultural business. In the first year of the rule, the Department estimates that the average employer will spend approximately 6 minutes each week or approximately 5 hours a year (based on a 50 week average period of need) to prepare and store the records, which amounts to approximately \$392.40 ($\78.48×5) in labor costs per year.⁹⁴ For the 485 employers, the total is 2,425 minutes (485 employers \times 5 minutes) per week, or 40 hours per week for recording, with an annualized reporting burden of 2,000 hours per year (40 hours per week \times 50 weeks). The total recordkeeping burden for 485 employers is 485 minutes (485 employers \times 1 minute) per week, or 8 hours per week, with an annualized recordkeeping burden of 400 hours per year (8 hours per week \times 50 weeks). When these two sums are added together, the total employer reporting and recordkeeping burden is 2,400 hours per year. Therefore, the total annual respondent hourly cost for this new reporting and recordkeeping burden placed on the employers in herding and the range production of livestock is estimated at 2,400 hours \times $\$78.48 = \0.19 million per year.

n. Time To Read and Review the Rule

During the first year that this rule would be in effect, herding and range livestock production employers would need to learn about the new requirements. The Department received a couple of comments related to the cost to read and review the proposed rule, which expressed the view that the Department's estimate was too low. For example, Sheep! Magazine commented

⁹⁴ The Department estimates that herding and range livestock production employers will spend 5 minutes each week to record and 1 minute to store these records. The average period of need for an H-2A worker is 50 weeks a year. The median hourly wage for a human resources manager is \$54.88 (as published by the Department's OES survey, O*Net Online), which we multiply by 1.43 to account for private-sector employee benefits (Source: Bureau of Labor Statistics). This calculation yields an hourly labor cost of \$78.48.

that it would take longer than two hours to read and review the proposed rule. The commenter stated that the average American cannot read 400 words per minute, especially when reading regulatory language. Vermillion Ranch and Midland Ranch stated that the Department's estimate of the average annual cost (\$15.18) to review the NPRM was an underestimate because employers or associations would have to hire counsel and experts to review the NPRM and prepare feedback and guidance. The commenters suggested that it would cost \$15,000 per employer.

In response to comments, the Department revised its estimate of time to read and review the Final Rule upward to four hours. While the Department understands that different employers may take more or less time to read and review the rule, it believes that four hours on average is a reasonable estimate of the time needed to learn about the new requirements. The text of the regulation is quite limited in length and scope as it addresses only the subset of requirements for herding and the range production of livestock that are exceptions from the standard H-2A regulations. Further, the Final Rule does not require employers to retain counsel or other advisors to assist them, and the Department will make available compliance assistance materials, including a specific small business compliance guide, that many employers may choose to read in lieu of reading the regulation itself.

i. Costs

This requirement represents a cost to herding and range livestock production employers in the first year of the rule. The Department notes that the cost of reading and reviewing the rule (\$313.92) is incurred only in the first year; amortized over the rule's 10-year lifespan, the average annual cost is only \$31.39. The Department estimates this cost by multiplying the time required to read and review the new rule (4 hours) by the average compensation of a human resources manager at an agricultural business (\$78.48).⁹⁵ The Department estimates the cost of reading and reviewing the rule by multiplying \$31.39 times the number of employers (485). This calculation results in a cost of \$152,251 in 2016 and an average annual cost of \$15,225.

⁹⁵ The median hourly wage for a human resources manager is \$54.88 (as published by the Department's OES survey, O*Net Online), which we multiply by 1.43 to account for private-sector employee benefits (source: Bureau of Labor Statistics). This calculation yields an hourly labor cost of \$78.48.

5. Summary of Impacts

i. Costs and Transfers

Exhibit 10 presents a summary of first-year and average annual costs and transfers by affected entity.⁹⁶ The Department estimates the total first-year costs and transfers of the Final Rule to be \$8.49 million and \$9.11 million, respectively. The transfer from all herding and range livestock production employers to workers due to the revised wage determination methodology, which bases the monthly AEWR on the forecasted ECI-adjusted \$7.25 base wage, times 48 hours per week with a 2-year transition period, amounts to \$9.11 million. The largest first-year cost is the cost to expand cooking/cleaning facilities at \$3.93 million, followed by the cost of providing water to workers, the cost of providing food to workers, recordkeeping, heating equipment, and the time required to read and review the Final Rule. These costs and transfers are incurred by all sheep and goat herding and range livestock production employers with the exception of the cost of providing food to workers, which is incurred only by range livestock production employers. Range livestock production employers experience a cost reduction of approximately \$0.06 million in the first year of the rule due to the elimination of the newspaper advertising requirement.

In general, average annual transfers are larger than those in the first year because of the transition period for the monthly wage increases and because the Department adjusted the base wage based upon the wages and salaries ECI over the 10-year analysis period. The average annual transfer from employers to employees due to the revised wage determination methodology for the AEWR amounts to \$17.46 million per year. The largest average cost is providing water to workers at \$2.36 million per year, followed by the cost of providing meals to workers at \$1.78 million per year, the cost of expanding cooking/cleaning facilities at \$0.75 million per year, the cost of recordkeeping at \$0.19 million per year, the cost of the heating equipment and propane at \$0.10 million, and the time required to read and review the Final Rule at \$0.02 million per year. Range livestock production employers experience an average annual cost

⁹⁶ Transfer payments, as defined by OMB Circular A-4, are payments from one group to another that do not affect total resources available to society. Transfer payments are associated with a distributional effect but do not result in additional costs or benefits to society. In this case, the Department classifies the wage increases as both transfer payments (to society) and costs (to employers).

reduction of approximately \$0.06 million. The Department estimates the

average annual cost of the Final Rule to be \$5.13 million.

EXHIBIT 10: SUMMARY OF COSTS AND TRANSFERS				
Required Action	Entity Affected	Monetized Year 1 Costs (\$millions)	Average Annual Costs (\$millions)	
Costs				
1	Proportion/type of work permitted at the ranch	All Employers	Not Monetized	Not Monetized
2	Filing requirements	Livestock Employers	Not Monetized	Not Monetized
3	Job order submissions	Livestock Employers	Not Monetized	Not Monetized
4	Job order duration	Herding Employers	Not Monetized	Not Monetized
5	Newspaper advertisements	Livestock Employers	(\$0.06)	(\$0.06)
6	Placement of workers on master applications	All Employers	Not Monetized	Not Monetized
7	Employer-provided items	All Employers	Not Monetized	Not Monetized
8	Meals	Livestock Employers	\$1.78	\$1.78
9	Water	All Employers	\$2.39	\$2.36
10	Expanded cooking/cleaning facilities	All Employers	\$3.93	\$0.75
11	Recordkeeping	All Employers	\$0.19	\$0.19
12	Heating equipment	All Employers	\$0.11	\$0.10
13	Time required to read and review the Rule	All Employers	\$0.15	\$0.02
Total Costs			\$8.49	\$5.13
Transfers				
1	New wage determination methodology based on the ECI-adjust \$7.25 hourly wage rate with the two-year transition	All Employers	\$9.11	\$17.46
Total Transfers			\$9.11	\$17.46

Exhibit 11 presents a summary of the economic impact analysis of the Final Rule. The monetized net costs and transfers displayed are the yearly summations of the calculations described above. In some cases, the totals for one year are less than the totals of the annual averages described

above. The total (undiscounted) costs and transfers of the rule sum to \$51.26 million and \$174.64 million over the 10-year analysis period, respectively. This amounts to an average annual cost and transfer of \$5.13 million and \$17.46 million per year, respectively. In total, the 10-year discounted costs of the Final

Rule range from \$36.87 million to \$44.16 million (with 7 and 3 percent discounting, respectively). In total, the 10-year discounted transfers of the Final Rule range from \$117.99 million to \$146.52 million (with 7 and 3 percent discounting, respectively).

EXHIBIT 11: SUMMARY OF MONETIZED COSTS/TRANSFERS			
Year		Net Costs (\$millions/year)	Transfers (\$millions/year)
1	2016	8.49	9.11
2	2017	4.75	12.80
3	2018	4.75	16.73
4	2019	4.75	17.39
5	2020	4.75	18.04
6	2021	4.75	18.70
7	2022	4.75	19.35
8	2023	4.75	20.07
9	2024	4.75	20.78
10	2025	4.75	21.67
Undiscounted total		51.26	174.64
Average annual impact		5.13	17.46
Total with 7% discounting		36.87	117.99
Total with 3% discounting		44.16	146.52

Note: Totals may not sum due to rounding.

ii. Benefits

The Department was able to identify cost reductions of the Final Rule due to the elimination of the newspaper advertising requirement, which amount to \$0.06 million per year over the 10-year analysis period. The Department also expects there to be cost reductions due to the revised job order submission requirements and the revised master application filing requirements. However, the Department was not able to quantify those cost reductions resulting from the Final Rule.

Due to data limitations, the Department also did not quantify several of the important benefits to society provided by the revised policies. Through this rulemaking the Department is establishing a new methodology for determining a monthly AEWR and clarifying employer obligations for these unique occupations with the aim of protecting the wages and working conditions of U.S. workers and better assessing their availability for these jobs based on appropriate terms and conditions of employment. The higher wages for workers will result in an improved ability on the part of workers and their families to meet their costs of living and spend money in their local communities. Higher wages may

also decrease turnover among U.S. workers and thereby decrease the costs of recruitment and retention to employers. Reduced worker turnover is associated with lower costs to employers arising from recruiting and training replacement workers. Because seeking and training new workers is costly, reduced turnover leads to savings for employers. Research indicates that decreased turnover costs partially offset increased labor costs (Reich, Hall, and Jacobs 2003; Fairris, Runstein, Briones, and Goodheart 2005).⁹⁷

This potential retention of U.S. workers may reduce the need to recruit and hire temporary foreign workers to fill these jobs. Furthermore, higher wages may have positive impacts on productivity. Higher wages can boost employee morale, thereby leading to

⁹⁷ Reich, Michael, Peter Hall, and Ken Jacobs, "Living Wages and Economic Performance: The San Francisco Airport Model" Institute of Industrial Relations, University of California, Berkeley, March 2003. Fairris, David, David Runsten, Carolina Briones, and Jessica Goodheart, "Examining the Evidence: The Impact of the Los Angeles Living Wage Ordinance on Workers and Businesses" LAANE, 2005. See Arindrajit Dube, T. William Lester and Michael Reich (2012), "Minimum Wage Shocks, Employment Flows and Labor Market Frictions," Institute for Research on Labor and Employment, <http://www.irle.berkeley.edu/workingpapers/122-12.pdf>.

increased effort and greater productivity. For example, Holzer (1990)⁹⁸ finds that high-wage firms can sometimes offset more than half of their higher wage costs through improved productivity and lower hiring and turnover costs.

In addition, clarifications for such requirements as providing sufficient housing; supplying all tools, supplies, and equipment required, free of charge; establishing effective means of communication in case of emergencies; and providing meals and potable water will better foster the safety and health of both U.S. and H-2A workers as they perform these jobs. Due to data limitations, the Department was not able to quantify or monetize the impact of these protective measures.

B. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) at 5 U.S.C. 603 requires agencies to prepare a regulatory flexibility analysis to determine whether a regulation will have a significant economic impact on a substantial number of small entities. Section 605 of the RFA allows an agency to certify a rule in lieu of

⁹⁸ Holzer, Harry, "Wages, Employer Costs, and Employee Performance in the Firm." Industrial and Labor Relations Review, Vol. 43, No. 3, pp 147-164, 1990.

preparing an analysis if the regulation is not expected to have a significant economic impact on a substantial number of small entities. Further, under the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 (SBREFA), an agency is required to produce compliance guidance for small entities if the rule has a significant economic impact. This rule will have a significant economic impact on a substantial number of small entities.

1. Need for, and Objectives of, the Rule

Among the reasons for the current rulemaking was the decision of the Court of Appeals for the District of Columbia in the *Mendoza* case, which required the Department to engage in notice and comment rulemaking to set standards governing the employment of foreign herders because those standards were legislative rules governed by the Administrative Procedure Act, 5 U.S.C. 553. *Mendoza*, 754 F.3d at 1024–1025. In addition to the *Mendoza* decision, ETA's traditional method of determining the monthly AEWR for these occupations—the use of SWA surveys—has become increasingly difficult with few states reporting wage results because their surveys included so few U.S. workers that they could not report statistically valid results. Wage stagnation has resulted from this methodology with herders in most states earning only slightly higher nominal wages today than they were 20 years ago, and therefore they are making significantly less in real terms. 80 FR 20307. Accordingly, we needed to engage in notice and comment rulemaking as a result of both the *Mendoza* decision and to address the faulty wage methodology that over years contributed to herder wage stagnation.

2. Significant Issues Raised by the Public Comments and the Department's Response

This section presents an analysis of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis (IRFA) and a summary of the Department's response to those issues. We discuss many of these issues in detail in the preamble and the EO 12866 analysis and, therefore, we incorporate those discussions by reference.

a. Comments on the Number of H–2A Workers per Small Business

The SBA Office of Advocacy, the Mountain Plains Agricultural Services and Western Range Association (Mountain Plains and Western Range), the Wyoming Wool Growers

Association, Vermillion Ranch and Midland Ranch, and others stated that the Department underestimated the cost of the proposed rule for small herding operations because these operations may hire more than three H–2A workers, which is the value the Department used to estimate costs. They emphasized that, for small businesses that hire more than three H–2A workers, the cost of the proposed rule could be higher than the 19 to 24 percent of revenues the Department identified in the IRFA. The commenters referenced a survey by the Colorado Wool Growers Association, *The Real Wage Benefits Provided to H–2A Sheep Herders and the Economic Cost to Colorado Ranchers*, which showed that its members hired an average of five H–2A workers per employer. The commenters also cited a recent phone survey by Mountain Plains, which showed that its members hired an average of 4.2 H–2A workers per employer. Vermillion Ranch and Midland Ranch stated that although their ranches' gross revenues are generally higher than the average annual revenue of \$252,050 estimated by the Department, they would incur significantly greater costs because they hire 18 and 13 workers, respectively, each year.

Some commenters provided the number of workers hired on their ranches per year:

- Etchart Livestock, Inc. stated that it employs five to seven foreign workers.
- David and Bonnie Little stated that they employ 10 shepherders.
- FIM Corp. stated that it employs 11 H–2A shepherders.
- Julian Land & Livestock stated that it employs 12 to 22 men.

In the Notice of Proposed Rulemaking (NPRM) economic analysis, the Department estimated the average number of H–2A workers per employer as three based on actual H–2A certifications issued during FY 2011 and FY 2012. Based on a review of more recent H–2A certifications issued during FY 2013 and FY 2014, the Department revised the average number H–2A workers per employer to 4.2 in the final regulatory flexibility analysis (FRFA).⁹⁹

⁹⁹ The FY 2013 and FY 2014 certification data show an annual average of 953 applications certified for an average of 2,481 workers in the herding and range production of livestock program, or 2.6 workers per application. The Department concluded that this could be an underestimate because some employers file multiple applications per year. Therefore, we also attempted to identify the number of unique employers filing applications. We estimate that an annual average of 485 unique employers filed applications, which would indicate 5.1 workers per employer. However, the Department concluded that this could be an overestimate because employers do not bring into

The Department notes that this is the average number of H–2A workers per employer, meaning that some employers may choose to employ more than 4.2 H–2A workers while others employ fewer. The Department agrees that ranchers involved in sheep and goat herding operations who employ more than 4.2 H–2A workers, and who earn no more than an average revenue of \$252,050, will incur a revenue loss of more than the estimated percentage of annual revenues. Based on the revised average number of H–2A workers per employer, the Department believes that the Final Rule will have a significant economic impact on a substantial number of affected small entities. DOL has a statutory obligation to set wages and working conditions in the H–2A program at a level that protects against adverse effect on U.S. workers due to the employment of foreign workers. For the reasons discussed in the preamble, DOL has determined that the requirements in this rule are needed to protect against adverse effect on U.S. workers; therefore, DOL could not lower requirements for small businesses.

b. Comments on the Calculation of the Number of Affected Small Entities

The Department received comments on the calculation of the number of affected small entities. The commenters asserted that most or all of the businesses affected by the proposed rule are small entities.

John and Carolyn Espil stated that most or all of the ranches affected by the proposed rule would be small entities. They cited (1) the Nevada Department of Agriculture (NDA), which stated that 82.78 percent of agricultural operations in Nevada are engaged in livestock production and (2) the NDA's Economic Contribution of Agriculture Report, which stated that 82.2 percent of farms and ranches are owned by families or individuals. The commenters also disagreed with the Department's estimate in the IRFA that the average small farm makes \$252,050 in annual revenue. The commenters remarked that farms cannot make this much without off-farm income and stated that any other estimates using this annual revenue figure should be considered inaccurate as well. Sharon O'Toole stated that since nearly all of the

the country all the workers for which they are certified each year. Furthermore, some employers file multiple applications because their itinerary changes and they need to reapply to receive authorization to send workers to another state, even though they will be the same workers. Therefore, we assumed an average of 4.2 workers per employer, consistent with the estimate from the Mountain Plains 2015 telephone survey of its members discussed by the SBA Office of Advocacy.

businesses affected by the proposed rule are small entities, the proposed rule is a violation of existing law.

Mountain Plains and Western Range and Texas Sheep & Goat Raisers Association cited the ASI, which stated that 99.98 percent of sheep operations in the United States are small businesses. In addition, the commenter noted that nearly all of the members of Mountain Plains and Western Range would meet the statutory definition of a "small business" for an agricultural enterprise. The SBA Office of Advocacy confirmed that approximately 99 percent of U.S. farms in the relevant industries are considered small businesses under the SBA definition. The Siddoway Sheep Company referenced the U.S. Department of Agriculture's most recent census, which stated that 92 percent of sheep and goat operations are family businesses. ASI and Public Lands Council and Patrick O'Toole stated that changes to the H-2A sheepherder program would have a significant negative impact on the 79,500 family farms and ranches that raise sheep in the United States. The Wyoming Livestock Board, the Texas Sheep & Goat Raisers Association, ASI, and the Pilster Ranch stated that 38 percent of sheep production in the United States is under the care of H-2A sheepherders and that the proposed rule would negatively impact the 79,500 family farms in the U.S. sheep industry.

The Department agrees with the commenters that almost all of the H-2A employers affected by the rule are small entities that meet the SBA's small business size standards, which was reflected in the IRFA and is repeated in the FRFA. However, the Department maintains that its estimate of the average revenue of a small entity (\$252,050 in 2013 dollars) is consistent with the average revenue from the Idaho farm enterprise budget for range sheep herding submitted by Mountain Plains and Western Range. Please note that in the FRFA, the Department has updated its analysis to 2014 dollars; thus, the revised estimate of the average revenue of a small entity is \$256,138 in 2014 dollars.¹⁰⁰ In addition, some ranchers have multiple enterprise operations that

include both range sheep production and range cattle production.

c. Comments on the Calculation of the Significant Economic Impact on a Substantial Number of Small Entities

The Department received several comments stating that the proposed rule would have a significant economic impact on a substantial number of small entities. The Department also received a couple of comments suggesting that the Department publish a Supplemental IRFA for public comment.

The SBA Office of Advocacy, Mountain Plains and Western Range, the Wyoming Wool Growers Association, the Montana Wool Growers Association, John and Carolyn Espil, and Sheep! Magazine concluded that the proposed rule would have a significant economic impact on a substantial number of small entities. The SBA Office of Advocacy stated that the Department's IRFA may have underestimated costs for small businesses and did not analyze any alternatives that may minimize the economic impact on small businesses. The commenter suggested that the Department publish for public comment a Supplemental IRFA analyzing the cost of the proposed rule and alternatives for small businesses that minimize the economic impact.

The Department concluded that the proposed rule would have a significant economic impact on a substantial number of small entities. Therefore, the Department published the IRFA and invited comments on the impact to such small entities. If the small-entity impact estimates in the IRFA underestimated the true costs to the small entities, such as because we were not able to quantify the costs of some of items due to data limitations, we specifically identified those items and invited comments. Very few, if any, responses were received that provided specific information on such costs. Moreover, the IRFA identified two alternatives; we did not identify any less costly alternatives because we concluded, at that time, that such alternatives would not allow the Department to fulfill our dual statutory mandate of determining that no U.S. workers are available for the job and that the employment of foreign workers will not adversely affect the wages and working conditions of workers similarly employed in the United States.

With respect to the "downstream" economic impacts on related industries in the U.S. economy, the Department was unable to quantify such impacts due to a lack of data and statistical input-output models necessary to conduct an accurate analysis. Therefore,

such impacts are beyond the scope of this economic analysis.

Based upon the comments received on the NPRM, the Final Rule makes a number of changes to the NPRM, all of which are analyzed below. The Department decided to set the monthly wage rates for range herders of sheep, goats, and other livestock using the current Fair Labor Standards Act (FLSA) minimum wage rate of \$7.25 per hour as a starting point, with annual adjustments to account for inflation, and an assumed 48-hour workweek; we also considered and address below alternative wage setting proposals submitted by commenters, including two less costly alternatives.

d. Alternatives Considered in the Analysis

As discussed in detail in the EO 12866 analysis, the Department received comments related to the alternatives considered in the IRFA. Many commenters asserted that the alternatives were not "true" alternatives in that the Department did not consider other ways to determine the monthly Adverse Effect Wage Rate (AEWR). They commented that the Department only considered alternatives related to the timing of the monthly wage rate increases, and thus they characterized it as one alternative with three transition periods. For this reason, some commenters stated that the Department failed to meet the requirements set forth in Section 603(c) of the RFA to describe "any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities."

The Department carefully reviewed the comments related to the proposed wage-setting methodology and to the alternatives laid out in the EO 12866 analysis and the IRFA. After considering the comments, the Department has decided to set the monthly AEWR for range herders of sheep, goats, and other livestock using a formula based on the current FLSA minimum wage as a starting point, with annual adjustment based on inflation. This decision is in line with the second of two alternative proposals set forth by Mountain Plains and Western Range, which was endorsed by the ASI and many individual employers; however, it also was slightly modified consistent with the suggestions in the Worker Advocates' Joint Comment. As discussed in detail in the preamble, the Department concludes that this wage rate is both necessary to provide a meaningful test of the labor market for

¹⁰⁰ According to the 2012 Census of Agriculture, the average revenue (*i.e.*, the average market value of agricultural products sold and government payments) per farm in the relevant industries is \$248,411. After adjusting for inflation using the CPI-U, the Department estimates that the average revenue per farm in the relevant industries is approximately \$252,050 in 2013 dollars and \$256,138 in 2014 dollars. Thus, the Department estimated that a small farm in the relevant industries would have average annual revenues of approximately \$252,050 and \$256,138 in the NPRM and Final Rule, respectively.

available U.S. workers and to protect against adverse effect on workers in the United States similarly employed.

The Department has considered three alternatives in addition to the new wage setting methodology in the Final Rule analysis:

(1) To base the monthly AEWR on the 1994 TEGL wage rates (\$800, which was approximately the highest 1994 TEGL rate), adjusted to a 2014 monthly wage using the ECI capped at a maximum annual increase of 2.5 percent, the forecasted ECI for wages and salaries values applied to the estimated 2014 monthly wage, and which is introduced over a three-year transition period with full implementation in year four;

(2) to base the monthly AEWR on the current FLSA minimum hourly wage, the forecasted ECI for wages and salaries values applied beginning in year five, a 44-hour workweek, and which is introduced over a three-year transition period with full implementation in year four; and

(3) to base the monthly AEWR on forecasted hourly AEWRs for combined field and livestock workers by state, a 65-hour workweek, with full implementation in year one, and incorporating a monthly food deduction estimate as permitted in the standard H-2A program, which is adjusted by the average CPI-U over 2012 to 2014.

The preamble and the EO 12866 analysis describe in detail the methodology we adopted in the Final Rule and the reasons for its selection over the three alternatives that we considered. The three alternatives that we considered are described in detail below.

i. 1994 TEGL Wage Adjusted Based on Capped ECI With a Three-Year Transition Period

Under this alternate wage determination methodology, the Department adjusts the estimated 1994 TEGL wage (\$800.00) as recommended by Mountain Plains, Western Range, ASI

and others using a capped ECI approach.¹⁰¹ Under the capped ECI approach, we adjust the wage for each year as follows:

- By 1.5 percent if the percentage increase in the wages and salaries ECI during the previous calendar year was less than 1.5 percent;
- By the percentage increase if the percentage increase in the wages and salaries ECI during the previous calendar year was between 1.5 percent and 2.5 percent, inclusive; or
- By 2.5 percent if the percentage increases in the wages and salaries ECI during the previous calendar year was greater than 2.5 percent.

¹⁰¹ The employer commenters proposed using \$800 as the 1994 wage to index; although \$800 is higher than the wage in all but one state, it was not used in any state and is lower than the \$820 sheep and goat herder wage in Arizona in 1994. The alternative wage methodology does not account for wages paid by livestock herders, which are not available for 1994.

EXHIBIT 12: CAPPED ECI INDEX APPROACH USED FOR ALTERNATIVE 1				
Year	4th Quarter Wages and Salaries ECI	Actual Percentage Change in ECI	Percentage Increase Applied (According to the Capped ECI Approach)	Capped Indexed Wage
1993	68.3	N/A	N/A	N/A
1994	70.3	2.8%	2.5%	\$800.00
1995	72.2	2.8%	2.5%	\$820.00
1996	74.7	3.4%	2.5%	\$840.50
1997	77.7	4.1%	2.5%	\$861.51
1998	80.7	3.8%	2.5%	\$883.05
1999	83.5	3.4%	2.5%	\$905.13
2000	86.7	3.9%	2.5%	\$927.75
2001	90.0	3.8%	2.5%	\$950.95
2002	92.3	2.6%	2.5%	\$974.72
2003	95.2	3.1%	2.5%	\$999.09
2004	97.7	2.6%	2.5%	\$1,024.07
2005	100.1	2.5%	2.5%	\$1,049.67
2006	103.3	3.2%	2.5%	\$1,075.91
2007	106.7	3.3%	2.5%	\$1,102.81
2008	109.5	2.6%	2.5%	\$1,130.38
2009	111.0	1.4%	1.5%	\$1,158.64
2010	112.9	1.7%	1.7%	\$1,176.02
2011	114.7	1.6%	1.6%	\$1,196.15
2012	116.7	1.7%	1.7%	\$1,215.22
2013	119.1	2.1%	2.1%	\$1,236.41
2014	121.7	2.2%	2.2%	\$1,261.84

We then apply the growth rate calculated under the Final Rule's source—the average year-to-year-growth rate of the average quarterly wages and salaries ECI for each year from 2012 through 2014 (2.0 percent)—to the 2014-

indexed wage (\$1,261.84) and forecast the indexed monthly wage required under Alternative 1 for 2016 to 2025. The wage rate determination methodology includes a three-year transition period, with full

implementation in year four. The Department estimates the hourly wage rate for each year of the analysis period as follows (Exhibit 13):

EXHIBIT 13: WAGE RATE TRANSITION SCHEDULE FOR ALTERNATIVE 1	
Year	Wage Rate Estimate
2016	80 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2017	85 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2018	90 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2019	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2020	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2021	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2022	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2023	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2024	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage
2025	100 percent of the forecasted ECI-adjusted cap-indexed 1994 TEGL wage

Exhibit 14 presents the forecasted ECI-adjusted cap-indexed 1994 TEGL wage with a three-year transition period

and full implementation in 2019 under Alternative 1.

EXHIBIT 14: FORECASTED ECI-ADJUSTED CAP INDEXED 1994 TEGL WAGE WITH A THREE-YEAR TRANSITION PERIOD									
2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
\$1,049	\$1,137	\$1,227	\$1,391	\$1,418	\$1,446	\$1,474	\$1,503	\$1,533	\$1,563

Exhibits 15 and 16 present the wage differential between the monthly wage under Alternative 1 and the baseline by state for sheep and goat herders and range livestock production workers, respectively. In the case of California and Oregon, the monthly wage under Alternative 1 is lower than the baseline wage in every year. In the case of

Hawaii, where the monthly wage of \$1,422.52 is based on a 2012 prevailing wage survey conducted by California, the monthly wage under Alternative 1 is lower than Hawaii's current baseline wage in the first five years. In these instances, the Department assumes that the workers will continue to receive the baseline wage in the applicable year;

therefore, no wage differential results. Additionally, the monthly wage differentials for states that did not have a baseline wage because there were no H-2A workers certified are denoted as "N/A." Note that these values are for informational purposes only and were not used in the analysis.

**EXHIBIT 15: MONTHLY WAGE DIFFERENTIAL BY STATE FOR SHEEP AND GOAT HERDERS
FOR ALTERNATIVE 1**

State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
AZ	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
AR	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
CA	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
CO	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
HI	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$23.26	\$51.65	\$80.59	\$110.09	\$140.18
ID	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
MO	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
MT	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
NE	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
NV	\$249.49	\$336.97	\$427.49	\$590.65	\$617.95	\$645.78	\$674.17	\$703.11	\$732.61	\$762.70
NM	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OK	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
OR	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
SD	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
TX	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
UT	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
WA	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70
WY	\$299.49	\$386.97	\$477.49	\$640.65	\$667.95	\$695.78	\$724.17	\$753.11	\$782.61	\$812.70

EXHIBIT 16: MONTHLY WAGE DIFFERENTIAL BY STATE FOR RANGE LIVESTOCK PRODUCTION WORKERS FOR ALTERNATIVE 1

State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AZ	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CO	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
HI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ID	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
MO	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MT	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
NE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NV	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
NM	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
ND	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
OK	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
OR	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
SD	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
TX	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
UT	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70
WA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
WY	\$174.49	\$261.97	\$352.49	\$515.65	\$542.95	\$570.78	\$599.17	\$628.11	\$657.61	\$687.70

ii. Forecasted ECI-Adjusted \$7.25 Multiplied by 44 Hours/Week With a Three-Year Transition Period

Under this alternate monthly wage rate determination methodology, which also was generally suggested by Mountain Plains, Western Range, ASI,

and other employer commenters, the Department estimates the hourly base wage rate by applying the 2-percent growth rate estimated under the Final Rule’s wage methodology, which is the average year-to-year-growth rate of the average quarterly ECI for wages and salaries for each year from 2012 through

2014, to \$7.25 for each year beginning in 2020.¹⁰² The wage rate determination methodology uses a three-year transition period, with full implementation in year four. The Department estimates the hourly wage rate for each year of the analysis period as follows (Exhibit 17):

¹⁰² Because the average year-to-year ECI growth rate was 2.0 percent, it fell within the cap range (1.5

to 2.5 percent) suggested by Mountain Plains and Western Range; therefore, the increase is the same

whether using the capped or uncapped methodology.

EXHIBIT 17: BASE WAGE RATE TRANSITION SCHEDULE FOR ALTERNATIVE 2	
Year	Base Wage Rate Estimate
2016	75 percent of the \$7.25
2017	80 percent of the \$7.25
2018	90 percent of the \$7.25
2019	100 percent of the \$7.25
2020	100 percent of the 2020 ECI-adjusted \$7.25
2021	100 percent of the 2021 ECI-adjusted \$7.25
2022	100 percent of the 2022 ECI-adjusted \$7.25
2023	100 percent of the 2023 ECI-adjusted \$7.25
2024	100 percent of the 2024 ECI-adjusted \$7.25
2025	100 percent of the 2025 ECI-adjusted \$7.25

To convert the hourly base wage rate to a monthly wage rate, the Department multiplies the hourly wage rate by 44 hours per workweek and 4.333 weeks per month. Exhibit 18 presents the monthly AEWR.

EXHIBIT 18: Monthly FORECASTED ECI-ADJUSTED \$7.25 BASE WAGE WITH A 44-Hour Week and THREE-YEAR TRANSITION PERIOD									
2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
\$1,037	\$1,106	\$1,245	\$1,382	\$1,409	\$1,438	\$1,466	\$1,495	\$1,523	\$1,554

Exhibits 19 and 20 present the wage differential between the monthly wage under Alternative 2 and the baseline by state for sheep and goat herders and range livestock production workers, respectively. In the case of California and Oregon, the monthly wage under Alternative 2 is lower than the baseline wage in every year. In the case of

Hawaii, where the monthly wage of \$1,422.52 is based on a 2012 prevailing wage survey conducted by California, the monthly wage under Alternative 2 is lower than Hawaii’s current baseline wage in the first five years. In these instances, the Department assumes that the workers will continue to receive the baseline wage in the applicable year;

therefore, no wage differential results. Additionally, the monthly wage differentials for states that did not have a baseline wage are denoted as “N/A.” Note that these values are for informational purposes only and were not used in the analysis.

**EXHIBIT 19: MONTHLY WAGE DIFFERENTIAL BY STATE FOR SHEEP AND GOAT HERDERS
FOR ALTERNATIVE 2**

State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
AZ	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
AR	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
CA	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
CO	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
HI	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$15.00	\$43.59	\$72.19	\$100.79	\$131.29
ID	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
MO	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
MT	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
NE	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
NV	\$237.15	\$305.78	\$444.96	\$582.23	\$608.92	\$637.52	\$666.11	\$694.71	\$723.31	\$753.81
NM	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OK	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
OR	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
SD	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
TX	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
UT	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
WA	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81
WY	\$287.15	\$355.78	\$494.96	\$632.23	\$658.92	\$687.52	\$716.11	\$744.71	\$773.31	\$803.81

**EXHIBIT 20: MONTHLY WAGE DIFFERENTIAL BY STATE FOR RANGE LIVESTOCK
PRODUCTION WORKERS FOR ALTERNATIVE 2**

State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AZ	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CO	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
HI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ID	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
MO	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MT	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
NE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NV	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
NM	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
ND	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
OK	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
OR	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
SD	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
TX	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
UT	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81
WA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
WY	\$162.15	\$230.78	\$369.96	\$507.23	\$533.92	\$562.52	\$591.11	\$619.71	\$648.31	\$678.81

iii. Forecasted FLS-Based AEW, 65-Hour Week, With Food Deductions and No Transition Period

Under this alternate wage rate determination methodology, based

generally upon the recommendation made in the Joint Workers' Advocate Comment, the Department first calculates the annual percentage change in each state's average FLS-based AEW

for each year from 2013 to 2015. We then take the averages of the resulting two values to estimate the average annual percentage changes by state as shown in Exhibit 21.

EXHIBIT 21: WAGE GROWTH RATE BY STATE FOR ALTERNATIVE 3						
Abbreviation	Actual FLS-Based AEW			Percent Change (2013–2014)	Percent Change (2014–2015)	Geometric Average Annual Percent Change (2013–2015)
	2013	2014	2015			
AL	\$9.78	\$10.00	\$10.00	2.2%	0.0%	1.1%
AZ	\$9.73	\$9.97	\$10.54	2.5%	5.7%	3.8%
AR	\$9.50	\$9.87	\$10.18	3.9%	3.1%	3.5%
CA	\$10.74	\$11.01	\$11.33	2.5%	2.9%	2.7%
CO	\$10.08	\$10.89	\$11.37	8.0%	4.4%	6.0%
HI	\$12.72	\$12.91	\$12.98	1.5%	0.5%	0.9%
ID	\$9.99	\$10.69	\$11.14	7.0%	4.2%	5.4%
MO	\$11.41	\$12.22	\$12.62	7.1%	3.3%	4.8%
MT	\$9.99	\$10.69	\$11.14	7.0%	4.2%	5.4%
NE	\$12.33	\$13.41	\$13.59	8.8%	1.3%	3.4%
NV	\$10.08	\$10.89	\$11.37	8.0%	4.4%	6.0%
NM	\$9.73	\$9.97	\$10.54	2.5%	5.7%	3.8%
ND	\$12.33	\$13.41	\$13.59	8.8%	1.3%	3.4%
OK	\$10.18	\$10.86	\$10.35	6.7%	-4.7%	0.8%
OR	\$12.00	\$11.87	\$12.42	-1.1%	4.6%	1.7%
SD	\$12.33	\$13.41	\$13.59	8.8%	1.3%	3.4%
TX	\$10.18	\$10.86	\$10.35	6.7%	-4.7%	0.8%
UT	\$10.08	\$10.89	\$11.37	8.0%	4.4%	6.0%
WA	\$12.00	\$11.87	\$12.42	-1.1%	4.6%	1.7%
WY	\$9.99	\$10.69	\$11.14	7.0%	4.2%	5.4%

Using each state's geometric average annual percent change, we forecast each state's FLS-based AEW for 2016 to 2025.¹⁰³

Using Alabama as an example, the geometric average annual percent

change over the two years is 1.1 percent. The Department applies the 1.1-percent growth rate to the 2015 hourly AEW to obtain the forecasted 2016 hourly AEW (\$10.00 × 1.011 = \$10.11). We then apply the same 1.1 percent growth rate to the forecasted 2016 hourly

AEW to forecast the 2017 hourly AEW (\$10.11 × 1.011 = \$10.22). We repeat this calculation to forecast the hourly AEWs for the remaining years in the analysis period. Exhibit 22 presents the forecasted hourly AEWs for each state.

$$r_{mean} = \sqrt{(1 + r_{2013-2014})(1 + r_{2014-2015})} - 1$$

¹⁰³ The geometric mean of the annual percent changes provides the rate of growth which, if experienced each year, would lead to the same total

change in wages as that observed between 2013 and 2015. In this case, the formula for the geometric mean is: (see equation above) where r_{mean} is the

geometric mean and $r_{2013-2014}$ and $r_{2014-2015}$ are the annual percent changes between 2013–2014 and 2014–2015, respectively.

EXHIBIT 22: FORECASTED FLS-BASED HOURLY AEWRs BY STATE

Abbreviation	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	\$10.11	\$10.22	\$10.34	\$10.45	\$10.57	\$10.69	\$10.81	\$10.93	\$11.05	\$11.18
AZ	\$10.94	\$11.35	\$11.77	\$12.21	\$12.67	\$13.15	\$13.64	\$14.16	\$14.69	\$15.24
AR	\$10.54	\$10.90	\$11.29	\$11.68	\$12.09	\$12.51	\$12.95	\$13.40	\$13.87	\$14.36
CA	\$11.64	\$11.95	\$12.27	\$12.61	\$12.95	\$13.30	\$13.66	\$14.02	\$14.40	\$14.79
CO	\$12.05	\$12.76	\$13.52	\$14.33	\$15.18	\$16.08	\$17.04	\$18.06	\$19.13	\$20.27
HI	\$13.10	\$13.21	\$13.33	\$13.45	\$13.57	\$13.70	\$13.82	\$13.94	\$14.07	\$14.20
ID	\$11.75	\$12.38	\$13.06	\$13.76	\$14.51	\$15.30	\$16.13	\$17.01	\$17.93	\$18.90
MO	\$13.23	\$13.87	\$14.53	\$15.24	\$15.97	\$16.74	\$17.55	\$18.39	\$19.28	\$20.21
MT	\$11.75	\$12.38	\$13.06	\$13.76	\$14.51	\$15.30	\$16.13	\$17.01	\$17.93	\$18.90
NE	\$14.06	\$14.54	\$15.04	\$15.55	\$16.09	\$16.64	\$17.21	\$17.80	\$18.41	\$19.04
NV	\$12.05	\$12.76	\$13.52	\$14.33	\$15.18	\$16.08	\$17.04	\$18.06	\$19.13	\$20.27
NM	\$10.94	\$11.35	\$11.77	\$12.21	\$12.67	\$13.15	\$13.64	\$14.16	\$14.69	\$15.24
ND	\$14.06	\$14.54	\$15.04	\$15.55	\$16.09	\$16.64	\$17.21	\$17.80	\$18.41	\$19.04
OK	\$10.44	\$10.52	\$10.61	\$10.70	\$10.79	\$10.88	\$10.97	\$11.06	\$11.15	\$11.24
OR	\$12.64	\$12.85	\$13.08	\$13.30	\$13.54	\$13.77	\$14.01	\$14.25	\$14.50	\$14.75
SD	\$14.06	\$14.54	\$15.04	\$15.55	\$16.09	\$16.64	\$17.21	\$17.80	\$18.41	\$19.04
TX	\$10.44	\$10.52	\$10.61	\$10.70	\$10.79	\$10.88	\$10.97	\$11.06	\$11.15	\$11.24
UT	\$12.05	\$12.76	\$13.52	\$14.33	\$15.18	\$16.08	\$17.04	\$18.06	\$19.13	\$20.27
WA	\$12.64	\$12.85	\$13.08	\$13.30	\$13.54	\$13.77	\$14.01	\$14.25	\$14.50	\$14.75
WY	\$11.75	\$12.38	\$13.06	\$13.76	\$14.51	\$15.30	\$16.13	\$17.01	\$17.93	\$18.90

As recommended in the Worker Advocates' Joint Comment, this wage rate option does not use a transition period. To convert the hourly FLS-based AEWR to a monthly wage rate, the Department multiplies the hourly wage rate by 65 hours per workweek and

4.333 weeks per month. To account for the food deduction, we convert the 2015 daily food deduction of \$11.86 per worker to the monthly food deduction of \$359.73 per worker by multiplying the daily food deduction by the number of days per week (7) by the number of

weeks per month (4.333).¹⁰⁴ We then apply the average year-to-year change in the CPI-U from 2012 to 2014 (1.5 percent) to the monthly food deduction for each year beginning in 2016. Exhibit 23 presents the monthly food deductions by year.

¹⁰⁴ The daily meal cost estimate of \$11.86 is from *Allowable Meal Charges and Reimbursements for Daily Subsistence* published by the U.S. Department

of Labor, Employment & Training Administration (Source: <http://www.foreignlaborcert.doleta.gov/>

meal_travel_subsistence.cfm. Accessed July 30, 2015).

EXHIBIT 23: MONTHLY CPI- ADJUSTED FOOD DEDUCTIONS FOR ALTERNATIVE 3	
Year	Monthly Deduction
2016	\$365.28
2017	\$370.92
2018	\$376.64
2019	\$382.45
2020	\$388.36
2021	\$394.35
2022	\$400.44
2023	\$406.62
2024	\$412.89
2025	\$419.27

We subtract the monthly food deduction from the monthly wage. Exhibit 24 presents the monthly wages

with the food deductions taken into account.

EXHIBIT 24: FORECASTED MONTHLY FLS-BASED AEWRs WITH FOOD DEDUCTIONS BY STATE											
Abbreviation	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	
AL	\$2,483	\$2,509	\$2,535	\$2,562	\$2,589	\$2,616	\$2,644	\$2,672	\$2,700	\$2,729	
AZ	\$2,715	\$2,825	\$2,939	\$3,058	\$3,181	\$3,309	\$3,442	\$3,580	\$3,724	\$3,873	
AR	\$2,602	\$2,700	\$2,802	\$2,907	\$3,017	\$3,130	\$3,247	\$3,368	\$3,494	\$3,624	
CA	\$2,912	\$2,995	\$3,080	\$3,168	\$3,258	\$3,350	\$3,446	\$3,543	\$3,644	\$3,747	
CO	\$3,028	\$3,224	\$3,432	\$3,653	\$3,887	\$4,136	\$4,399	\$4,679	\$4,975	\$5,289	
HI	\$3,323	\$3,351	\$3,379	\$3,407	\$3,435	\$3,463	\$3,492	\$3,521	\$3,550	\$3,579	
ID	\$2,943	\$3,117	\$3,300	\$3,494	\$3,699	\$3,915	\$4,143	\$4,383	\$4,637	\$4,905	
MO	\$3,360	\$3,534	\$3,717	\$3,908	\$4,109	\$4,320	\$4,541	\$4,773	\$5,017	\$5,272	
MT	\$2,943	\$3,117	\$3,300	\$3,494	\$3,699	\$3,915	\$4,143	\$4,383	\$4,637	\$4,905	
NE	\$3,594	\$3,724	\$3,858	\$3,998	\$4,142	\$4,291	\$4,446	\$4,606	\$4,772	\$4,943	
NV	\$3,028	\$3,224	\$3,432	\$3,653	\$3,887	\$4,136	\$4,399	\$4,679	\$4,975	\$5,289	
NM	\$2,715	\$2,825	\$2,939	\$3,058	\$3,181	\$3,309	\$3,442	\$3,580	\$3,724	\$3,873	
ND	\$3,594	\$3,724	\$3,858	\$3,998	\$4,142	\$4,291	\$4,446	\$4,606	\$4,772	\$4,943	
OK	\$2,574	\$2,593	\$2,612	\$2,631	\$2,650	\$2,669	\$2,689	\$2,708	\$2,728	\$2,747	
OR	\$3,193	\$3,250	\$3,307	\$3,365	\$3,424	\$3,484	\$3,545	\$3,607	\$3,671	\$3,735	
SD	\$3,594	\$3,724	\$3,858	\$3,998	\$4,142	\$4,291	\$4,446	\$4,606	\$4,772	\$4,943	
TX	\$2,574	\$2,593	\$2,612	\$2,631	\$2,650	\$2,669	\$2,689	\$2,708	\$2,728	\$2,747	
UT	\$3,028	\$3,224	\$3,432	\$3,653	\$3,887	\$4,136	\$4,399	\$4,679	\$4,975	\$5,289	
WA	\$3,193	\$3,250	\$3,307	\$3,365	\$3,424	\$3,484	\$3,545	\$3,607	\$3,671	\$3,735	
WY	\$2,943	\$3,117	\$3,300	\$3,494	\$3,699	\$3,915	\$4,143	\$4,383	\$4,637	\$4,905	

Exhibits 25 and 26 present the wage differential between the monthly wage under Alternative 3—the forecasted FLS-based AEWR with food deductions taken into account—and the baseline by

state for sheep and goat herders and range livestock production workers, respectively. Additionally, the monthly wage differentials for states that did not have a baseline wage because there were

no H-2A workers employed as herders or range livestock workers are denoted as “N/A.” Note that these values are for informational purposes only and were not used in the analysis.

EXHIBIT 25: MONTHLY WAGE DIFFERENTIAL BY STATE FOR SHEEP AND GOAT HERDERS FOR ALTERNATIVE 3										
State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	\$1,733	\$1,759	\$1,785	\$1,812	\$1,839	\$1,866	\$1,894	\$1,922	\$1,950	\$1,979
AZ	\$1,965	\$2,075	\$2,189	\$2,308	\$2,431	\$2,559	\$2,692	\$2,830	\$2,974	\$3,123
AR	\$1,852	\$1,950	\$2,052	\$2,157	\$2,267	\$2,380	\$2,497	\$2,618	\$2,744	\$2,874
CA	\$1,134	\$1,217	\$1,302	\$1,390	\$1,480	\$1,573	\$1,668	\$1,765	\$1,866	\$1,969
CO	\$2,278	\$2,474	\$2,682	\$2,903	\$3,137	\$3,386	\$3,649	\$3,929	\$4,225	\$4,539
HI	\$1,901	\$1,928	\$1,956	\$1,984	\$2,012	\$2,041	\$2,069	\$2,098	\$2,127	\$2,157
ID	\$2,193	\$2,367	\$2,550	\$2,744	\$2,949	\$3,165	\$3,393	\$3,633	\$3,887	\$4,155
MO	\$2,610	\$2,784	\$2,967	\$3,158	\$3,359	\$3,570	\$3,791	\$4,023	\$4,267	\$4,522
MT	\$2,193	\$2,367	\$2,550	\$2,744	\$2,949	\$3,165	\$3,393	\$3,633	\$3,887	\$4,155
NE	\$2,844	\$2,974	\$3,108	\$3,248	\$3,392	\$3,541	\$3,696	\$3,856	\$4,022	\$4,193
NV	\$2,228	\$2,424	\$2,632	\$2,853	\$3,087	\$3,336	\$3,599	\$3,879	\$4,175	\$4,489
NM	\$1,965	\$2,075	\$2,189	\$2,308	\$2,431	\$2,559	\$2,692	\$2,830	\$2,974	\$3,123
ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OK	\$1,824	\$1,843	\$1,862	\$1,881	\$1,900	\$1,919	\$1,939	\$1,958	\$1,978	\$1,997
OR	\$1,590	\$1,621	\$1,653	\$1,686	\$1,719	\$1,753	\$1,788	\$1,823	\$1,858	\$1,895
SD	\$2,844	\$2,974	\$3,108	\$3,248	\$3,392	\$3,541	\$3,696	\$3,856	\$4,022	\$4,193
TX	\$1,824	\$1,843	\$1,862	\$1,881	\$1,900	\$1,919	\$1,939	\$1,958	\$1,978	\$1,997
UT	\$2,278	\$2,474	\$2,682	\$2,903	\$3,137	\$3,386	\$3,649	\$3,929	\$4,225	\$4,539
WA	\$2,443	\$2,500	\$2,557	\$2,615	\$2,674	\$2,734	\$2,795	\$2,857	\$2,921	\$2,985
WY	\$2,193	\$2,367	\$2,550	\$2,744	\$2,949	\$3,165	\$3,393	\$3,633	\$3,887	\$4,155

**EXHIBIT 26: MONTHLY WAGE DIFFERENTIAL BY STATE FOR RANGE LIVESTOCK PRODUCTION
WORKERS FOR ALTERNATIVE 3**

State	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
AL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AZ	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AR	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CO	\$2,153	\$2,349	\$2,557	\$2,778	\$3,012	\$3,261	\$3,524	\$3,804	\$4,100	\$4,414
HI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ID	\$2,068	\$2,242	\$2,425	\$2,619	\$2,824	\$3,040	\$3,268	\$3,508	\$3,762	\$4,030
MO	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MT	\$2,068	\$2,242	\$2,425	\$2,619	\$2,824	\$3,040	\$3,268	\$3,508	\$3,762	\$4,030
NE	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NV	\$2,153	\$2,349	\$2,557	\$2,778	\$3,012	\$3,261	\$3,524	\$3,804	\$4,100	\$4,414
NM	\$1,840	\$1,950	\$2,064	\$2,183	\$2,306	\$2,434	\$2,567	\$2,705	\$2,849	\$2,998
ND	\$2,719	\$2,849	\$2,983	\$3,123	\$3,267	\$3,416	\$3,571	\$3,731	\$3,897	\$4,068
OK	\$1,699	\$1,718	\$1,737	\$1,756	\$1,775	\$1,794	\$1,814	\$1,833	\$1,853	\$1,872
OR	\$1,590	\$1,621	\$1,653	\$1,686	\$1,719	\$1,753	\$1,788	\$1,823	\$1,858	\$1,895
SD	\$2,719	\$2,849	\$2,983	\$3,123	\$3,267	\$3,416	\$3,571	\$3,731	\$3,897	\$4,068
TX	\$1,699	\$1,718	\$1,737	\$1,756	\$1,775	\$1,794	\$1,814	\$1,833	\$1,853	\$1,872
UT	\$2,153	\$2,349	\$2,557	\$2,778	\$3,012	\$3,261	\$3,524	\$3,804	\$4,100	\$4,414
WA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
WY	\$2,068	\$2,242	\$2,425	\$2,619	\$2,824	\$3,040	\$3,268	\$3,508	\$3,762	\$4,030

As discussed in the preamble and the EO 12866 analysis, the Department concludes that the Final Rule's methodology for setting the monthly AEWFR is the most appropriate as it will begin to address immediately and

substantially the wage stagnation that has occurred over the past decades. Some transition period is necessary because the comments indicate that requiring the full monthly increase immediately could lead to significant

disruptions that might cause job losses due to some employers going out of business or scaling back their operations. Based on all the information in the comments, including balance sheet information from individual

employers, the state enterprise budgets, and the other data in the record such as regarding average prices for lamb and wool over the last 15 years, the Department concludes that given the Final Rule's methodology for setting the monthly AEWR a two-year transition period is sufficient to avoid such disruptions. We do not believe that the lengthier transition periods in the first two alternatives we considered are necessary. However, we also do not believe that the third alternative, with substantially higher wages based on the FLS-based hourly wages with no transition period, is appropriate; the evidence indicates that there is a substantial risk that tripling the required wage rates will entirely eliminate annual profits for some employers,

which is likely to cause, rather than prevent, adverse effect on U.S. workers.

Exhibit 27 presents a summary of average annual transfers over the 10-year analysis period by wage determination methodology. The Department estimates the average annual transfer from all herding and range livestock production employers to workers due to the Final Rule's wage determination methodology, which bases the monthly AEWR on forecasted ECI-adjusted \$7.25 base wage, times 48 hours per week with a 2-year transition period, to be \$17.46 million per year. This is a decrease relative to the average annual transfer from employers to workers estimated under the NPRM's wage determination methodology, forecasted AEWR values by USDA

region incrementally phased in over a 5-year period, of \$45.08 million per year. Of the three alternatives, the largest average annual transfer from employers to employees due to Alternative 3's revised wage determination methodology (*i.e.*, the forecasted FLS-based AEWR with food deductions taken into account) amounts to \$71.38 million per year, followed by Alternative 1's methodology (*i.e.*, the forecasted ECI-adjusted cap-indexed 1994 TEGL wage with a 3-year transition period and full implementation in 2019) at \$12.64 million per year, and Alternative 2's methodology (*i.e.*, the forecasted ECI-adjusted \$7.25 base wage, times 44 hours per week with a 3-year transition period) at \$12.47 million per year.

EXHIBIT 27: SUMMARY OF AVERAGE ANNUAL TRANSFERS BY WAGE DETERMINATION METHODOLOGY	
Wage Determination Methodology	Average Annual Transfer (\$millions/year)
Final Rule	\$17.46
NPRM	\$45.08
Alternative 1	\$12.64
Alternative 2	\$12.47
Alternative 3	\$71.38

Note: The costs associated with the Final Rule and the three alternatives are in 2014 dollars, while that for the NPRM is in 2013 dollars.

3. Response to Comments Filed by the Chief Counsel for Advocacy of the SBA

As discussed in Section 2 above, the SBA Office of Advocacy submitted substantive comments regarding a number of issues, including the number of H-2A workers per small business, the calculation of the number of affected small entities, and the calculation of the significant impact on a substantial number of small entities. This section summarizes separately the SBA Office of Advocacy's comments and the Department's responses.

The SBA Office of Advocacy commented that the Department underestimated the cost of the proposed rule for small herding operations because these operations may hire more than three H-2A workers, which is the value the Department used to estimate costs. In response to this concern, the Department revised the average number of H-2A workers per employer in the FRFA to 4.2 based on actual H-2A certifications issued during FY 2013 and FY 2014. This figure is consistent with

the estimate submitted by the commenters based upon a recent telephone survey conducted by Mountain Plains involving responses from 214 of 275 members.

The SBA Office of Advocacy also commented on the number of small entities affected, noting that approximately 99 percent of sheep operations in the United States are small businesses. The Department agrees that almost all of the H-2A employers affected by the proposed rule are small entities that meet the SBA's small business size standards, which was reflected in the IRFA and is repeated in the FRFA. However, the Department maintains that its estimate of the average revenue of a small entity (\$252,050 in 2013 dollars) is consistent with the average revenue from farm enterprise budgets for range sheep herding reported by commenters. Please note that in the FRFA, the Department updates its analysis to 2014 dollars; thus, the revised estimate of the average revenue of a small entity is \$256,138.

The SBA Office of Advocacy stated that the proposed rule would have a significant impact on a substantial number of small entities. SBA also commented that the Department's IRFA may have underestimated costs for small businesses and did not analyze any alternatives that may minimize the economic impact on small businesses. SBA suggested that the Department publish for public comment a Supplemental IRFA analyzing the cost of the proposed rule and alternatives for small businesses that minimize the economic impact. The Department concluded that the proposed rule would have a significant impact on a substantial number of small entities. Therefore, the Department published the IRFA and invited comments on the impact to such small entities. If we were not able to quantify certain costs due to data limitations, we identified those items and invited comments. Very few, if any, responses were received that provided specific information on such costs.

The IRFA identified two alternatives for setting the required monthly wage; we did not identify any less costly alternatives in the IRFA because we concluded, at that time, that such alternatives would not allow the Department to fulfill its dual statutory mandate of ensuring that no U.S. workers are available for the job and that the employment of foreign workers will not adversely affect the wages and working conditions of workers similarly employed in the United States. Based upon comments received from the industry, the FRFA identifies two less-costly alternatives to the Final Rule wage methodology and, together with the preamble and EO 12866 analysis, explains why the Department did not find either of those alternatives to be appropriate.

The SBA Office of Advocacy expressed concern about the NPRM's definition of "open range," noting that 36 percent of respondents to a Mountain Plains survey thought they would not qualify for the program if fences were prohibited. The Final Rule substantially revises the definition of what qualifies as the "range" in recognition of the fact that fences are used in many locations for many purposes, including on Forest Service and BLM lands where animals graze.

The SBA Office of Advocacy also expressed concern that the NPRM relied upon the same hourly wage rate as is paid to regular H-2A field and livestock workers, when herding employers provide housing, food, clothing, tools, paid vacation, etc. Unlike the NPRM, the Final Rule does not base the monthly AEWR on the FLS-based hourly wage. Moreover, we note that all H-2A employers are required to provide free housing and are required to provide the tools, supplies and equipment necessary to perform the job free of charge. The Department does not require herding employers to provide paid vacation, although we support them if they voluntarily choose to do so.

With regard to the concern that small herding operations have a difficult time hiring U.S. workers for this work, we anticipate that updating the required monthly wage rate to overcome the many years of wage stagnation may result in more U.S. workers being interested in this work. California, which has a higher state minimum wage for herders, is consistently among the states with the largest number of U.S. shepherders identified in SWA surveys.

4. Calculation of the Number of Affected Small Entities

a. Definition of a Small Business

A small entity is one that is "independently owned and operated and which is not dominant in its field of operation." The definition of small business varies from industry to industry, to the extent necessary, in order to properly reflect industry size differences. An agency must either use the SBA definition for a small entity or establish an alternative definition for the relevant industries to which a rule applies, which in this case includes Beef Cattle Ranching and Farming (NAICS 112111), Dairy Cattle and Milk Production (NAICS 11212), Sheep and Goat Farming (NAICS 1124), and Other Animal Production (NAICS 1129).¹⁰⁵ The Department has adopted the SBA definition for these industries, which is an establishment with annual revenues of less than \$0.75 million.¹⁰⁶

b. Estimated Number of Affected Small Entities

Approximately 99 percent of U.S. farms in the relevant industries have annual revenues of less than \$0.75 million and, therefore, fall within the SBA's definition of a small entity. The Department estimates that by 2025, there will be approximately 485 employer applications filed (not necessarily applicants) under the H-2A program for herding and the range production of livestock. The Department considers a rule to have an impact on a "substantial number of small entities" when the total number of small entities impacted by the rule is equal to or greater than 15 percent of the relevant universe of small entities affected in a given industry (in this case, the relevant universe is the employers participating in the program). Therefore, the Department concludes the rule will have an impact on a substantial number of small entities as described by the RFA.

¹⁰⁵ Animal Aquaculture (NAICS 1125) is not considered a relevant industry for this rulemaking. However, the RFA analysis uses data from the 2012 Census of Agriculture, which does not distinguish between Animal Aquaculture (1125) and Other Animal Production (1129). Due to this data limitation, the Department includes Animal Aquaculture industry data in the calculations of this RFA analysis. In addition, the Department excludes farms in the Cattle Feedlots (NAICS 112112) industry because cattle in feedlots do not graze on the range; therefore, employers in the cattle feedlot industry would not be affected by the rule.

¹⁰⁶ Source: U.S. Small Business Administration. *Table of Small Business Size Standards Matched to North American Industry Classification System Codes* (July 2014). Available at http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf (Accessed Nov. 13, 2014).

5. Compliance Requirements of the Final Rule, Including Reporting and Recordkeeping

a. Impact on Small Businesses

The Department has estimated the incremental costs for small businesses from the baseline (*i.e.*, the 2010 Final Rule, TEGL 32-10, and TEGL 15-06, Change 1) to this rule. We have estimated the costs of (a) the new methodology for estimating the minimum monthly AEWR employers must offer to their workers; (b) elimination of requirements to advertise in a newspaper of general circulation in the area of intended employment (cost reduction); (c) provision of meals; (d) provision of potable water; (e) provision of expanded cooking/cleaning facilities at the ranch; (f) recording and retaining records of the employees' work locations; (g) providing heating equipment; and (h) time to read and review the rule. This analysis includes the incremental cost of this rule as it adds to the requirements in the 2010 Final Rule, TEGL 32-10, and TEGL 15-6, Change 1. The cost estimates included in this analysis for the provisions of the Final Rule are consistent with those presented in the EO 12866 section.

The Department identified the following provisions of the Final Rule to have an impact to industry but was not able to quantify the impacts due to data limitations: proportion/type of work permitted at the ranch (*i.e.*, not on the range); application filing requirements; job order submissions; job order duration; placement of workers on master applications; and employer-provided items. Thus, although the Department believes those additional costs are minor, the total cost to small entities may be higher than the total cost presented in this analysis (although we conclude the cost of other items may be overestimated).

i. New Methodology for Estimating the Wages of Workers

Under the new wage determination methodology, the use of the forecasted ECI-adjusted \$7.25 base wage times 48 hours per week and times 4.333 weeks per month to set the required monthly AEWR, with a two-year transition period, results in an increase of \$1.53 in hourly wages (using the assumed 48 hours per week computation) paid to H-2A workers in 2016. The Department multiplies this average hourly wage increase by 48 hours per workweek to obtain a weekly cost per worker of \$73.44 ($\1.53×48) in 2016. The Department then multiplies this weekly cost by 50 weeks, which is the average

period of need for workers in these industries. This results in an average increased cost of \$3,672.00 ($\73.44×50) per H-2A worker in 2016. For employers hiring the average number of H-2A workers (4.2), this results in an average increased cost of \$15,422.40 ($\$3,672 \times 4.2$) paid to workers in wages for 2016.

To estimate the average annual cost of increased wages paid to H-2A workers under the Final Rule's wage determination methodology, the Department first calculates the average annual assumed hourly wage increase over the period of analysis. Given the average annual assumed hourly wage increase (\$2.93), a 48-hour workweek, and an average period of need for workers of 50 weeks, the Department estimates an average annual increased cost of \$7,039.20 ($\$2.93 \times 48 \times 50$) per H-2A worker. For employers hiring the average number of H-2A workers (4.2), this results in an average annual increased cost of \$29,564.64 ($\$7,039.20 \times 4.2$) paid to workers in wages over the 10-year analysis period.¹⁰⁷

To estimate the average annual cost of increased wages paid to H-2A workers under the first wage determination methodology alternative—the forecasted ECI-adjusted cap-indexed 1994 TEGL wage with a three-year transition—the Department first calculates the average annual monthly wage increase over the period of analysis. Given the average annual monthly wage increase (\$441.66), an average period of need for workers of 11.54 months,¹⁰⁸ the Department estimates an average annual increased cost of \$5,096.71 ($\441.66×11.54) per H-2A worker. For employers hiring the average number of H-2A workers (4.2), this alternative results in an average annual increased cost of \$21,406.19 ($\$5,096.71 \times 4.2$) paid to workers in wages over the 10-year analysis period.

To estimate the average annual cost of increased wages paid to H-2A workers under the second wage determination methodology alternative—the forecasted ECI-adjusted \$7.25 wage rate with a

¹⁰⁷ If the results of the FRFA, using an estimated average of 4.2 workers per employer, were multiplied times 485 (the number of employers), it would not produce identical results to the total impact results estimated in the EO 12866 analysis. As we discussed above, the Department concludes that the EO 12866 analysis produces an overestimate of the likely results, in part because that analysis was based on an assumption that all 2,481 workers for whom employers receive a labor certification enter the country each year. The FRFA uses an estimate of 4.2 workers per employer, which mirrors the estimate from the Mountain Plains 2015 telephone survey of its members and is based upon estimates from the Department's data from H-2A applications for labor certification.

¹⁰⁸ 11.54 months are equivalent to 50 weeks.

three-year transition based on a 44-hour workweek—the Department calculates the average annual hourly wage increase over the period of analysis. Given the average annual hourly wage increase (\$2.28), a 44-hour workweek, and an average period of need for workers of 50 weeks, the Department estimates an average annual cost of \$5,024.80 ($\$2.28 \times 44 \times 50$) per H-2A worker. For employers hiring the average number of H-2A workers (4.2), this alternative results in an average annual increased cost of \$21,104.16 ($\$5,024.80 \times 4.2$) paid to workers in wages.

To estimate the average annual cost of increased wages paid to H-2A workers under the third wage determination methodology alternative—the forecasted State AEW with food deductions based on a 65-hour workweek—the Department calculates the average annual hourly wage increase over the period of analysis. Given the average annual hourly wage increase (\$8.85), a 65-hour workweek, and an average period of need for workers of 50 weeks, the Department estimates an average annual increased cost of \$28,772.25 ($\$8.85 \times 65 \times 50$) per H-2A worker. For employers hiring the average number of H-2A workers (4.2), this results in an average annual increased cost of \$120,843.45 ($\$28,772.25 \times 4.2$) paid to workers in wages.

ii. Newspaper Advertisements

Through the Final Rule, the Department will expand to production of livestock occupations on the range the historical practice of waiving the regulatory requirement to place two advertisements in a newspaper serving the area of intended employment for sheepherding and goat herding occupations. This will result in a minor cost reduction. To estimate this cost reduction, the Department multiplies the number of newspaper advertisements required for each range livestock employer application (2) by the average cost of placing a newspaper advertisement (\$258.64) to obtain an avoided cost of purchasing advertising space equal to \$517 ($2 \times \258.64) per range livestock employer application per year.¹⁰⁹ The Department also estimates the labor cost required to prepare the advertisements by multiplying the number of newspaper advertisements required per open range livestock production employer (2) by the assumed time required to prepare a

¹⁰⁹ The newspaper advertisement cost estimate is based on an advertisement of 158 words placed in *The Salt Lake Tribune* for one day. Available at <http://placead.yourutahclassifieds.com/webbase/en/std/jsp/WebBaseMain.do> (Accessed Nov. 13, 2014).

newspaper advertisement (0.5 hours) and the hourly compensation of a human resources (HR) manager (\$78.48), which amounts to \$78.48 ($2 \times 0.5 \times \78.48) in avoided labor costs per range livestock employer application per year.¹¹⁰ In total, this requirement will result in a cost reduction of \$595.76 ($\$517.28 + \78.48) per application per year for employers involved in the range production of livestock.

iii. Meals

Under the Final Rule, the Department will require H-2A employers to provide either three sufficient meals per day or free and convenient kitchen facilities and food provisions to workers. This change represents a cost to range livestock production employers but not to sheepherding or goat herding employers because this is already a requirement under TEGL 32-10. To estimate this cost, the Department multiplies the number of days per week workers receive meals (7) by the average daily cost of meals (\$11.86) and the average duration of need in weeks (50) to obtain a cost of \$4,151.00 ($7 \times \11.86×50) per range livestock production worker per year.¹¹¹ For employers hiring the average number of 4.2 H-2A workers, the average annual cost increase is \$17,434.20 ($\$4,151 \times 4.2$).

In addition to the cost to purchase food, range livestock production employers would also incur costs to transport the food to the workers. The Department assumes that food would be transported to the workers on a weekly basis along with the potable water. The costs related to transporting food and potable water are accounted for below in the section on costs related to potable water.

iv. Potable Water

The Final Rule requires that the herding or range livestock production employer provide to the workers adequate provision of potable water (4.5 gallons per day) for drinking and cooking, which is similar to the TEGLs' requirement. The Final Rule continues

¹¹⁰ The Department assumes estimates that range livestock production employers will spend 0.5 hours to prepare each newspaper advertisement. In addition, the Department estimates that the median hourly wage for a human resources manager is \$54.88 (as published by the Department's OES survey, O*Net Online), which we increased by 1.43 to account for private-sector employee benefits (Source: Bureau of Labor Statistics) for an hourly compensation rate of \$78.48.

¹¹¹ The meal cost estimate of \$11.86 is from *Allowable Meal Charges and Reimbursements for Daily Subsistence* published by the U.S. Department of Labor, Employment and Training Administration (source: http://www.foreignlaborcert.doleta.gov/meal_travel_subsistence.cfm; accessed on July 30, 2015).

the TEGLs' requirements for water for bathing and adds a requirement for sufficient water for laundry, although the Final Rule does not define a specific minimum quantity for these purposes. Moreover, the Final Rule allows employers to identify an alternate readily available source of water for bathing and laundry. The Department estimates the additional cost of these requirements above the baseline by summing the cost of purchasing the water, the cost of purchasing a trailer to transport the water and meals, the cost of vehicle mileage, and the labor cost of the time required to transport the water and meals to the workers.

As discussed above, in the NPRM the Department assumed that each worker required 28 gallons of water per worker per week. Several commenters stated that this was not a sufficient amount and suggested the Department use an estimate based on 4 to 4.5 gallons of potable water per day in clean and sealed containers. In the Final Rule, the Department revises this assumption to be 4.5 gallons of potable water per day, which amounts to approximately 31.5 gallons of potable water per worker per week (4.5 × 7).

The Department estimates the cost of purchasing the water by multiplying the cost per gallon of potable water (\$0.005) by the number of gallons of water per worker per week (31.5) and the average duration of need in weeks (50). This calculation yields a cost of providing potable water equal to \$7.88 ($\$0.005 \times 31.5 \times 50$) per worker per year and \$33.08 ($\7.88×4.2) for employers hiring the average number of 4.2 H-2A workers.¹¹²

The Department estimates the cost of purchasing a utility trailer to be \$839.34.¹¹³ This results in a one-time cost of \$839.34 for the average employer who must purchase a trailer in the first year of the rule. This value yields an average annual cost of \$83.93 over the 10-year analysis period.

The Department estimates the cost of vehicle mileage per employer by multiplying the average vehicle mileage cost (\$0.58) by the number of miles driven to transport the potable water and meals roundtrip (100) and the average number of roundtrips per year

¹¹² The potable water cost estimate is calculated using data published in the 2014 *Water and Wastewater Survey* produced by the Texas Municipal League. (Source: <http://www.tml.org/surveys>. Accessed Nov. 13, 2014). The estimate is based on the average cost of potable water for commercial entities in all Texas cities with a population below 2,000 using the fee for 50,000 gallons.

¹¹³ The trailer cost estimate is based on the average cost for a 5 × 8 ft. utility trailer from Tractor Supply Co., Lowes, and Home Depot.

(50).¹¹⁴ This calculation yields a mileage cost equal to \$2,900.00 ($\$0.58 \times 100 \times 50$) per employer per year.

The Department estimates the labor cost of time to transport the water and meals to workers by multiplying the average number of roundtrips required per employer (50) by the assumed time required to transport the water and meals (2.86 hours) and the hourly compensation of an agricultural worker (\$13.40), which amounts to \$1,916.20 ($50 \times 2.86 \times \13.40) in labor costs per employer per year.^{115 116}

Finally, the Department sums the cost of purchasing water, the cost of purchasing a trailer to transport the water and meals, the cost of vehicle mileage, and the labor cost of the time required to transport the water and meals to the workers. This requirement will result in a cost of \$5,663.42 ($\$7.88 + \$839.34 + \$2,900.00 + \$1,916.20$) per employer hiring only one H-2A worker during the first year of the rule. The average annual cost of this provision for employers hiring only one H-2A worker is \$4,908.01 ($\$7.88 + \$83.93 + \$2,900.00 + \$1,916.20$) over the 10-year analysis period. For employers hiring the average number of 4.2 H-2A workers, the first-year cost increases to \$5,688.62 ($\$33.08 + \$839.34 + \$2,900.00 + \$1,916.20$) and the average annual cost increases to \$4,933.21 ($\$33.01 + \$83.93 + \$2,900.00 + \$1,916.20$).

v. Expanded Cooking/Cleaning Facilities

Where a worker continues to use the mobile housing that was provided by the employer for herding or production of livestock operations on the range while the worker is temporarily stationed at the ranch to perform production of livestock duties (which includes those that are closely and

¹¹⁴ The cost per mile of owning and operating an automobile is based on the average costs in the DOT Bureau of Transportation Statistics. (Source: http://www.rita.dot.gov/bts/sites/rita.dot.gov/bts/files/publications/national_transportation_statistics/html/table_03_17.html. Accessed Nov. 13, 2014), which cites the costs presented by American Automobile Association Exchange (Source: <http://exchange.aaa.com/automobiles-travel/automobiles/driving-costs/>. Accessed July 30, 2015).

¹¹⁵ The Department assumes that a roundtrip would be 100 miles and that an agricultural worker would drive at 35 mph. We divide the 100 miles by 35 mph to estimate that it would take an agricultural worker 2.86 hours to drive roundtrip (100/35).

¹¹⁶ The Department assumes estimates that herding and range livestock production employers will spend 2.86 hours transporting water and meals. In addition, the Department estimates that the median hourly wage for an agricultural worker is \$9.37 (as published by the Department's OES survey, O*Net Online), which we increased by 1.43 to account for private-sector employee benefits (Source: Bureau of Labor Statistics) for an hourly wage rate of \$13.40.

directly related to herding and/or the production of livestock), the Final Rule requires that the employer provide the worker with access to facilities such as toilets and showers with hot and cold water under pressure. To estimate this cost, the Department multiplies the average cost per square foot to construct/expand cleaning facilities (\$270.00) by the assumed size of the facility that will be required to be constructed/expanded (150 square feet). This calculation results in a one-time cost of \$40,500.00 ($\270.00×150) for the average employer who must construct such a facility, which amounts to an average annual cost of \$4,050.00 over the 10-year analysis period.¹¹⁷

vi. Heating Equipment

In the Final Rule, as specified in § 655.235, the mobile housing unit provided to workers must include operable heating equipment that supplies adequate heat for workers in locations where necessary for the health and safety of workers due to the climate. The Department estimates the average cost per portable gas heating unit is \$150.00 and the propane cost to adequately supply heat for workers in locations where the temperature is expected to drop below 50 degrees Fahrenheit is \$969.00 per year.¹¹⁸ This calculation results in the total cost of \$1,119.00 ($\$150.00 + \969.00) for the average employer who must purchase the equipment, which amounts to an average annual cost of \$984.00 ($\$150.00 + \969.00) over the 10-year analysis period.

vii. Maintaining Records of Work Location

In response to comments, including from small businesses, the Final Rule modifies the NPRM's proposed recordkeeping requirements by eliminating the requirement to record hours worked when workers are not on the range and by eliminating the requirement to record the duties performed each day when workers are not on the range. The Final Rule retains only the requirement to record daily whether work was performed on the range or at the farm or ranch so that the Department can evaluate employers' compliance with the requirement that herding and range livestock workers must spend at least 50 percent of the job order period on the range.

The Department estimates the cost by multiplying the time required to prepare

¹¹⁷ The Department assumes that the average employer will require a cleaning facility of approximately 150 square feet.

¹¹⁸ $\$969.00 = \3×323 gallons.

and store the records by the average compensation of a human resources manager at an agricultural business. In the first year of the rule, the Department estimates that the average employer will spend approximately 6 minutes each week or approximately 5 hours a year (based on a 50 week average period of need) to prepare and store the records, which amounts to approximately \$392.40 ($\78.48×5) in labor costs per year.¹¹⁹ For the 485 employers, the total is 2,425 minutes (485 employers \times 5 minutes) per week, or 40 hours per week for recording, with an annualized reporting burden of 2,000 hours per year (40 hours per week \times 50 weeks). The total recordkeeping burden for 485 employers is 485 minutes (485 employers \times 1 minute) per week, or 8 hours per week, with an annualized recordkeeping burden of 400 hours per year (8 hours per week \times 50 weeks). When these two sums are added together, the total employer reporting and recordkeeping burden is 2,400 hours per year. Therefore, the total annual respondent hourly cost for this new reporting and recordkeeping burden placed on the employers in herding and the range production of livestock is estimated at 2,400 hours \times $\$78.48 = \$188,352$ per year.

viii. Time to Read and Review the Final Rule

During the first year that the Final Rule would be in effect, employers involved in the herding or production of livestock on the range would need to learn about the rule provisions and the

¹¹⁹ The Department estimates that herding and range livestock production employers will spend 5 minutes each week to record and 1 minute to store these records. The average period of need for an H-2A worker is 50 weeks a year. The median hourly wage for a human resources manager is \$54.88 (as published by the Department's OES survey, O*Net Online), which we multiply by 1.43 to account for private-sector employee benefits (Source: Bureau of Labor Statistics). This calculation yields an hourly labor cost of \$78.48.

requirements necessary to remain compliant. In the first year of the rule, the Department estimates that the average small farm will spend approximately 4 hours of staff time to read and review the new rule, which amounts to approximately \$313.92 ($\78.48×4) in labor costs per employer in the first year of the rule. This amounts to an average annual cost of \$31.39 ($\$313.92/10$) over the 10-year analysis period.¹²⁰

b. Total Cost Burden for Small Entities

The Department's calculations indicate that the total average annual cost is \$39,955.64 (or 15.6 percent of annual revenues) for the average small entity employing 4.2 workers in sheepherding or goat herding occupations.¹²¹ The total average annual cost is \$56,794.08 (or 22.2 percent of annual revenues) for the average small entity employing 4.2 workers in range livestock production occupations.¹²²

For small entities that apply for one worker instead of 4.2—representing the smallest of the small farms that hire workers—the Department estimates that the total average annual cost of the rule is \$17,405.00 (or 6.8 percent of annual revenues) for entities employing a worker in a sheepherding or goat

¹²⁰ The Department estimates that employers will spend 2 hours to read the new rule. In addition, the Department estimates that the median hourly wage for a human resources manager is \$54.88 (as published by the Department's OES survey, O*Net Online), which we increased by 1.43 to account for private-sector employee benefits (Source: Bureau of Labor Statistics) for an hourly compensation rate of \$78.48.

¹²¹ For illustration, the total average annual cost of \$39,939.95 for the results from summing the average annual totals for the various rule requirements described above as follows: $\$39,939.95 = \$29,565.64 + \$4,933.21 + \$4,050.00 + \$984.00 + \$392.40 + \$15.70$.

¹²² For illustration, the total average annual cost of \$56,778.39 results from summing the totals for the various rule requirements described above as follows: $\$56,778.39 = \$29,564.64 + \$595.76 + \$17,434.20 + \$4,933.21 + \$4,050.00 + \$984.00 + \$392.40 + \$15.70$.

herding occupation.¹²³ The Department estimates that the total average annual cost of the rule is \$20,960.24 (or 8.2 percent of annual revenues) for small entities applying for one worker in a range livestock production occupation.¹²⁴

Exhibit 28 presents a summary of the average annual cost per employer. The Department focuses on the average annual cost of the rule rather than costs in the first year because the wage methodology increases the costs of compliance over the analysis time period. The total cost per employer varies depending on whether the employer is a sheepherding or goat herding employer or a range livestock production employer. The Department defines a "significant economic impact" as an impact that amounts to at least three percent of annual revenues. Due primarily to the increase in wages paid to H-2A workers, the proposed rule is expected to have a significant economic impact on affected small entities. The average annual costs reflected in Exhibit 28 are an overestimate for most employers as they would apply only to an employer who must bear all the possible costs, including purchasing a trailer to deliver water, constructing a cleaning facility, and purchasing portable heating equipment. Because those costs apply to only a small percentage of the participating employers, the actual average annual cost for most employers will be substantially less than the cost shown.

¹²³ For illustration, the total average annual cost of \$17,389.31 results from summing the totals for the various rule requirements described above as follows: $\$17,389.31 = \$7,039.20 + \$4,908.01 + \$4,050.00 + \$984.00 + \$392.40 + \$15.70$.

¹²⁴ For illustration, the total average annual cost of \$20,944.55 results from summing the totals for the various rule requirements described above as follows: $\$20,944.55 = \$7,039.20 + \$595.76 + \$4,151 + \$4,908.02 + \$4,050.00 + \$984.00 + \$392.40 + \$15.70$.

EXHIBIT 28 : SUMMARY OF COSTS PER EMPLOYER			
Provision	Entity Affected	Average Annual Cost Per Employer	
		Hiring 1 Worker	Hiring 4.2 Workers
(a) New wage determination methodology based on the ECI-adjusted \$7.25 base wage with two-year transition period based on a 48-hour workweek	All Employers	\$7,039.20	\$29,564.64
(b) Newspaper advertisements	Livestock Employers	(\$595.76)	(\$595.76)
(c) Meals	Livestock Employers	\$4,151.00	\$17,434.20
(d) Potable water	All Employers	\$4,908.01	\$4,933.21
(e) Expanded cooking/cleaning facilities	All Employers	\$4,050.00	\$4,050.00
(f) Heating equipment	All Employers	\$984.00	\$984.00
(g) Recordkeeping	All Employers	\$392.40	\$392.40
(h) Time required to read and review the Final Rule	All Employers	\$31.39	\$31.39
Average Annual Revenue		\$256,138	
Total Annual Cost Per Shepherding/Goatherding Employer		\$17,405.00	\$39,955.64
Average Annual Cost as a Percentage of Revenue		6.8%	15.6%
Total Annual Cost Per Livestock Employer		\$20,960.24	\$56,794.08
Average Annual Cost as a Percentage of Revenue		8.2%	22.2%

c. Alternatives to the Final Rule

The Department has considered three alternatives to the wage methodology contained in the Final Rule, in which the monthly AEWR is based on the current FLSA minimum hourly wage as a starting point (*i.e.*, the \$7.25 hourly wage rate), the forecasted ECI for wages and salaries as published by the BLS applied beginning in year two, a 48-hour workweek, 4.333 weeks per month, and is introduced over a two-year transition period with full implementation in year three. Those three alternatives are: (1) To base the monthly AEWR on the 1994 TEGL wages (\$800) adjusted to the 2014 monthly wage using the ECI capped at 2.5 percent, the forecasted annual ECI for wages and salaries values applied to the estimated 2014 monthly wage, and to introduce it over a three-year transition period with full implementation in year four; (2) to base the monthly AEWR on the FLSA

minimum hourly wage, the forecasted ECI for wages and salaries values applied beginning in year five, a 44-hour workweek, and to introduce over a three-year transition period with full implementation in year four; and (3) to base the monthly AEWR on forecasted hourly AEWRs for combined field and livestock workers by state, a 65-hour workweek, with full implementation in year one, incorporating a monthly food deduction estimate, which is adjusted by the average CPI-U over 2012 to 2014.

The Department believes that the option adopted in the Final Rule will most effectively enable the Department to meet its statutory obligations to determine that there are not sufficient workers available to perform the labor or services requested, and that the employment of foreign workers will not adversely affect the wages and working conditions of workers in the United States similarly employed before the admission of foreign workers is

permitted, given these occupations and their unique characteristics that have historically resulted in a limited number of U.S. workers interested in performing these jobs. The new wage methodology will begin to address immediately the wage stagnation concerns discussed earlier.

Exhibit 29 presents a summary of the average annual cost per employer for the Final Rule, the NPRM, and the three alternatives. The Final Rule and three alternatives vary only due to their respective revised wage determination methodologies. Note that the average annual cost per employer for the NPRM is in 2013 dollars and did not include annual costs associated with earnings records or heating equipment. In each case, the total cost per employer varies depending on whether the employer is a shepherding or goat herding employer or a range livestock production employer.

EXHIBIT 29 : SUMMARY OF COSTS PER EMPLOYER BY ALTERNATIVE										
Provision	Hiring 1 Worker					Hiring 4.2 Workers				
	Final Rule	NPRM	Alt. 1	Alt. 2	Alt. 3	Final Rule	NPRM	Alt. 1	Alt. 2	Alt. 3
Average Annual Revenue	\$256,138									
Total Annual Cost Per Shepherding/ Goatherding Employer	\$17,405	\$21,486	\$15,463	\$15,391	\$39,138	\$39,956	\$65,861	\$31,797	\$31,495	\$131,234
Average Annual Cost as a Percentage of Revenue	6.8%	8.4%	6.0%	6.0%	15.3%	15.6%	25.7%	12.4%	12.3%	51.2%
Total Annual Cost Per Livestock Employer	\$20,960	\$24,946	\$19,018	\$18,946	\$42,693	\$56,794	\$82,290	\$48,636	\$48,334	\$148,073
Average Annual Cost as a Percentage of Revenue	8.2%	9.7%	7.4%	7.4%	16.7%	22.2%	32.1%	19.0%	18.9%	57.8%

The Department estimated the total cost burden on small entities for each of the alternatives as follows.

i. Forecasted ECI-Adjusted Cap-Indexed 1994 TEGL Wage With a Three-Year Transition Period

The first alternative retains the same features of the 2010 Final Rule, TEGL 32–10, TEGL 15–06, Change 1, and includes the same provisions as the Final Rule except that the wage determination methodology uses the forecasted ECI-adjusted cap-indexed 1994 TEGL wage with a three-year transition period. The Department's calculations indicate that the total average annual cost of this alternative would be \$31,797.19 (or 12.4 percent of annual revenues) for the average small entity employing 4.2 workers in sheepherding or goat herding occupations.¹²⁵ The total average annual cost of this alternative would be \$48,635.63 (or 19.0 percent of annual revenues) for the average small entity employing 4.2 workers in range livestock production occupations.¹²⁶

For small entities that apply for one worker instead of 4.2—representing the smallest of the small farms that hire workers—the Department estimates that the total average annual cost of this alternative would be \$15,462.51 (or 6.0 percent of annual revenues) for entities employing a worker in a sheepherding or goat herding occupation.¹²⁷ The total average annual cost of this alternative would be \$19,017.75 (or 7.4 percent of annual revenues) for small entities employing a worker in a range livestock production occupation.¹²⁸

¹²⁵ For illustration, the total average annual cost of \$31,781.49 for the average small entity applying for 4.2 workers in sheepherding or goat herding occupations results from summing the totals for the various rule requirements described above as follows: $\$31,781.49 = \$5,096.71 \times 4.2 + \$7.88 \times 4.2 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

¹²⁶ For illustration, the total average annual cost of \$48,619.93 for the average small entity applying for 4.2 workers in range livestock production occupations results from summing the totals for the various rule requirements described above as follows: $\$48,619.93 = \$5,096.71 \times 4.2 - \$595.76 + 4,151.00 \times 4.2 + \$7.88 \times 4.2 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \$15.70$.

¹²⁷ For illustration, the total average annual cost of \$15,446.82 for the average small entity applying for one worker in a sheepherding or goat herding occupation results from summing the totals for the various rule requirements described above as follows: $\$15,446.82 = \$5,096.71 + \$7.88 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

¹²⁸ For illustration, the total average annual cost of \$19,002.06 for the average small entity applying for one worker in a range livestock production occupation results from summing the totals for the various rule requirements described above as follows: $\$19,002.06 = \$5,096.71 - \$595.76 +$

ii. Forecasted ECI-Adjusted \$7.25 Wage Rate With a Three-Year Transition Period

The second alternative retains the same features of the 2010 Final Rule, TEGL 32–10, TEGL 15–06, Change 1, and includes the same provisions as the Final Rule except that the wage determination methodology uses a three-year transition period and is based on a 44-hour workweek. The Department's calculations indicate that the total average annual cost of this alternative would be \$31,495.16 (or 12.3 percent of annual revenues) for the average small entity employing 4.2 workers in sheepherding or goat herding occupations.¹²⁹ The total average annual cost of this alternative would be \$48,333.60 (or 18.9 percent of annual revenues) for the average small entity employing 4.2 workers in range livestock production occupations.¹³⁰

For small entities that apply for one worker instead of 4.2—representing the smallest of the small farms that hire workers—the Department estimates that the total average annual cost of this alternative would be \$15,390.60 (or 6.0 percent of annual revenues) for entities employing a worker in a sheepherding or goat herding occupation.¹³¹ The total average annual cost of this alternative would be \$18,945.84 (or 7.4 percent of annual revenues) for small entities employing a worker in a range livestock production occupation.¹³²

$\$4,151.00 + \$7.88 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \$15.70$.

¹²⁹ For illustration, the total average annual cost of \$31,479.47 for the average small entity applying for 4.2 workers in sheepherding or goat herding occupations results from summing the totals for the various rule requirements described above as follows: $\$31,479.47 = \$5,025 \times 4.2 + \$7.88 \times 4.2 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

¹³⁰ For illustration, the total average annual cost of \$48,317.91 for the average small entity applying for 4.2 workers in range livestock production occupations results from summing the totals for the various rule requirements described above as follows: $\$48,317.91 = \$5,024.80 \times 4.2 - \$595.76 + 4,151.00 \times 4.2 + \$7.88 \times 4.2 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \$15.70$.

¹³¹ For illustration, the total average annual cost of \$15,374.91 for the average small entity applying for one worker in a sheepherding or goat herding occupation results from summing the totals for the various rule requirements described above as follows: $\$15,374.91 = \$5,024.80 + \$7.88 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

¹³² For illustration, the total average annual cost of \$18,930.15 for the average small entity applying for one worker in a range livestock production occupation results from summing the totals for the various rule requirements described above as follows: $\$18,930.15 = \$5,024.80 - \$595.76 + \$4,151.00 + \$7.88 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

iii. Forecasted Hourly State AEWR With Food Deductions and No Transition Period

The third alternative retains the same features of the 2010 Final Rule, TEGL 32–10, TEGL 15–06, Change 1, and includes the same provisions as the Final Rule except that the wage determination methodology uses the forecasted state AEWR with food deductions, does not utilize a transition period, and is based on a 65-hour workweek. The Department's calculations indicate that the total average annual cost of this alternative would be \$131,234.45 (or 51.2 percent of annual revenues) for the average small entity employing 4.2 workers in sheepherding or goat herding occupations.¹³³ The total average annual cost of this alternative would be \$148,072.89 (or 57.8 percent of annual revenues) for the average small entity employing 4.2 workers in range livestock production occupations.¹³⁴

For small entities that apply for one worker instead of 4.2—representing the smallest of the small farms that hire workers—the Department estimates that the total average annual cost of this alternative would be \$39,138.05 (or 15.3 percent of annual revenues) for entities employing a worker in a sheepherding or goat herding occupation.¹³⁵ The total average annual cost of this alternative would be \$42,693.29 (or 16.7 percent of annual revenues) for small entities employing a worker in a range livestock production occupation.¹³⁶

¹³³ For illustration, the total average annual cost of \$133,552.91 for the average small entity applying for 4.2 workers in sheepherding or goat herding occupations results from summing the totals for the various rule requirements described above as follows: $\$133,552.91 = \$29,328.00 \times 4.2 + \$7.88 \times 4.2 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

¹³⁴ For illustration, the total average annual cost of \$150,391.35 for the average small entity applying for 4.2 workers in range livestock production occupations results from summing the totals for the various rule requirements described above as follows: $\$150,391.35 = \$29,328.00 \times 4.2 - \$595.76 + 4,151.00 \times 4.2 + \$7.88 \times 4.2 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \$15.70$.

¹³⁵ For illustration, the total average annual cost of \$39,678.11 for the average small entity applying for one worker in a sheepherding or goat herding occupation results from summing the totals for the various rule requirements described above as follows: $\$39,678.11 = \$29,328.00 + \$7.88 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

¹³⁶ For illustration, the total average annual cost of \$43,233.35 for the average small entity applying for one worker in a range livestock production occupation results from summing the totals for the various rule requirements described above as follows: $\$43,233.35 = \$29,328.00 - \$595.76 + \$4,151.00 + \$7.88 + \$83.93 + \$2,900.00 + \$1,916.20 + \$4,050.00 + \$984.00 + \$392.39 + \15.70 .

6. Steps Taken To Minimize the Economic Impact on Small Entities

This Final Rule will have a significant economic impact on a substantial number of small entities. We recognize the concerns expressed by small businesses and have made every effort to minimize the burden on all users to the extent consistent with DOL's obligations under the INA. The Department's responsibilities under the INA, however, severely constrain our ability to make adjustments to program requirements in an effort to address concerns unique to small business. The Department's mandate under the H-2A program is to set requirements for employers who wish to recruit and hire foreign agricultural workers. Those standards are designed to provide both that foreign workers are hired only if qualified domestic workers are not available and that bringing in H-2A workers will not adversely affect the wages and working conditions of similarly employed domestic workers. These regulations set those standards for range herding occupations. To create different and likely lower standards for small businesses would essentially sanction the very adverse effect that the Department is compelled to prevent. The need for parity among employers regardless of size is illuminated by the fact that Congress within the INA carved out a specific dispensation for small businesses in a specific area of the statute. Section 218(c)(3)(B)(ii) of the INA (8 U.S.C. 1188(c)(3)(B)(ii)) exempts certain small businesses from the application of the 50-percent rule regarding the period that priority hiring rights for U.S. applicants exist. Where Congress has so clearly demonstrated its ability to modify H-2A program requirements to accommodate small businesses, it would be inappropriate and outside of the Secretary's authority for the Department to carve out additional exceptions. Moreover, because commenters indicated that more than 99 percent of sheep operations in the United States qualify as small businesses under the SBA definition, there is no basis for considering special relief for small businesses.

As previously discussed, after considering the comments, DOL determines that it is appropriate and consistent with the Department's obligation to protect against adverse effect to U.S. workers to set the monthly AEW for these occupations by borrowing the current federal minimum wage of \$7.25/hour, multiplied by an estimated 48 hours per week, and adjusted annually based on the ECI. In

reaching this result, DOL concludes that the wage source proposed in the NPRM was likely to result in adverse effect to U.S. workers by causing a substantial number of herding employers to close or significantly downsize their operations. In addition to other reasons discussed fully above, we conclude that \$7.25/hour is an appropriate starting point to set the monthly rate because the persistent lack of workers in these herding occupations is likely due in part to the reality that U.S. workers can earn at least the federal minimum wage elsewhere. We use the uncapped ECI to adjust wages beginning in year two to require that wages in these occupations continue to rise apace with wages across the U.S. economy and adopt an estimate of 48 hours worked per week, a calculation from data reported on Form ETA-9142A, because it is the most comprehensive and detailed data source from which to establish an hourly calculation. In light of the scope of the increase and the economic data provided by commenters, discussed above, a transition period to the new wage is needed. Recognizing that any transition must not be longer than necessary to prevent adverse effect, we adopt a two-year transition with full implementation in year three. As noted above, the Final Rule does not provide any different wage or implementation period for small businesses, as virtually all employers subject to the Rule are small businesses. However, we believe that the Final Rule's monthly AEW methodology (which was modeled on one of the methodologies suggested by the three leading industry representatives), together with the other changes made in the Final Rule, such as those relating to the definition of the "range" and the deletion of the 20 percent cap on incidental work at the ranch, will allow small businesses to continue to participate successfully in the program.

In addition to the wage methodology adopted, DOL considered several significant alternative methodologies for setting the monthly AEW. First, we considered setting the monthly wage rate based on the 1994 TEGL wages adjusted based on the capped ECI, with a three-year transition and full implementation in year four as recommended by Mountain Plains, Western Range, and many others including individual small employers. As discussed further above, we do not adopt this recommendation because it is premised on a misunderstanding of the 1994 data in the NPRM. Further, given the absence of any data to assess an appropriate year and wage rate to index,

and what many commenters characterize as the persistent lack of U.S. workers in these occupations for decades, we are concerned that continued reliance on the TEGL wages, even in indexed form, could be inconsistent with DOL's obligation to protect against adverse effect on U.S. workers. In addition, capping the ECI as recommended by commenters would lead to further wage stagnation.

Second, we considered setting the monthly AEW by borrowing the current federal minimum wage rate of \$7.25/hour and multiplying it by 44 hours per week, with a three-year transition and full implementation in year four, using the capped ECI to adjust wages after year four as recommended by Mountain Plains, Western Range and many individual small employers. As discussed fully above, we have adopted the \$7.25 rate from this recommendation as the starting point, but have used a 48-hour estimate rather than a 44-hour estimate so that the hourly estimate is based on the most comprehensive data source available. Recognizing that any transition must not be longer than necessary to prevent adverse effect, this Final Rule requires a two-year transition, rather than the three-year transition recommended by these commenters.

Third, we considered setting the monthly wage rate using the FLS-based AEW, multiplied by a compromise number of weekly hours (65) between the data submitted by workers from the Colorado Legal Services survey, which found that 62 percent of herders worked at least 81 hours per week, and the 48-hour estimate from the Form ETA-9142A data. This option would have been implemented immediately and permitted a food deduction. As discussed above, DOL did not elect to use the FLS-based AEW to set the monthly wage rate because we conclude that the FLS-based methodology is likely to cause adverse effect to U.S. workers by causing a substantial number of herding employers to close or significantly downsize their operations—leaving fewer herding jobs available to U.S. workers and creating significant economic dislocation. We do not adopt a 65-hour threshold because this Final Rule relies only on the Form ETA-9142A data, the most comprehensive and detailed data source from which to establish an hourly calculation, rather than the calculation based on worker data in a single state. Finally, we do not require immediate implementation because we conclude that a brief transition period is needed for the reasons discussed above.

C. *Unfunded Mandates Reform*

Executive Order 12875—This Final Rule will not create an unfunded Federal mandate upon any State, local or tribal government.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. This Final Rule has no Federal mandate, which is defined in 2 U.S.C. 658(6) to include either a “Federal intergovernmental mandate” or a “Federal private sector mandate.” A Federal mandate is any provision in a regulation that imposes an enforceable duty upon State, local, or Tribal governments, or imposes a duty upon the private sector which is not voluntary. A decision by a private entity to obtain an H–2A worker is purely voluntary and is, therefore, excluded from any reporting requirement under the Act.

The SWAs are mandated to perform certain activities for the Federal Government under this program, and are compensated for the resources used in performing these activities.

This Final Rule includes no new mandates for the SWAs in the H–2A application process and does not include any Federal mandate that may result in increased expenditures by State, local, and tribal governments, in the aggregate, of \$100 million or more. It also does not result in increased expenditures by the private sector of \$100 million or more, because participation in the H–2A program is entirely voluntary. SWA activities under the H–2A program are currently funded by the Department through grants provided under the Wagner-Peyser Act. 29 U.S.C. 49 *et seq.* The Department anticipates continuing funding under the Wagner-Peyser Act. As a result of this Final Rule, the Department will analyze the amounts of such grants made available to each State to fund the activities of the SWAs.

D. *Small Business Regulatory Enforcement Fairness Act of 1996*

The Department has determined that this Final Rule will impose a significant economic impact on a substantial number of small entities under the RFA; therefore, the Department will be required to produce a Compliance Guide for Small Entities as mandated by SBREFA. The Department has concluded that this Final Rule is not a major rule requiring review by the Congress under SBREFA because it will

not likely result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local Government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

E. *The Congressional Review Act*

The Congressional Review Act (5 U.S.C. 801 *et seq.*) requires rules to be submitted to Congress before taking effect. We will submit to Congress and the Comptroller General of the United States a report regarding the issuance of this Final Rule prior to its effective date, as required by 5 U.S.C. 801(a)(1).

F. *Executive Order 13132—Federalism*

The Department has reviewed this Final Rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have federalism implications. The Final Rule does not have substantial direct effects on States, on the relationship between the States, or on the distribution of power and responsibilities among the various levels of Government as described by E.O. 13132. Therefore, the Department has determined that this Final Rule will not have a sufficient federalism implication to warrant the preparation of a summary impact statement.

G. *Executive Order 13175—Indian Tribal Governments*

This Final Rule was reviewed under the terms of E.O. 13175 and determined not to have Tribal implications. The Final Rule does not 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. As a result, no Tribal summary impact statement has been prepared.

H. *Assessment of Federal Regulations and Policies on Families*

Section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681) requires the Department to assess the impact of this NPRM on family well-being. A rule that is determined to have a negative effect on families must be

supported with an adequate rationale. The Department has assessed this Final Rule and determines that it will not have a negative effect on families.

I. *Executive Order 12630—Government Actions and Interference With Constitutionally Protected Property Rights*

This Final Rule is not subject to E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

J. *Executive Order 12988—Civil Justice*

This Final Rule has been drafted and reviewed in accordance with E.O. 12988, Civil Justice Reform, and will not unduly burden the Federal court system. The regulation has been written to minimize litigation and provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

K. *Plain Language*

The Department drafted this Final Rule in plain language.

L. *Executive Order 13211—Energy Supply*

This Final Rule is not subject to E.O. 13211. It will not have a significant adverse effect on the supply, distribution, or use of energy.

M. *Paperwork Reduction Act*

As part of its continuing effort to reduce paperwork and respondent burden, the Department of Labor (the Department) conducts a preclearance consultation process to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)).

This helps to ensure that the public understands the Department’s collection instructions; respondents can provide the requested data and in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number as required in 5 CFR 1320.11(l).

The information collected is mandated in this Final Rule at § 655.210(f). The Department did not create a specific form for this new

collection requirement. The Final Rule requires that employers keep daily records indicating the site of the employee's work, whether it was on the open range or on the ranch or farm. Any absences from work for which the employer prorates a worker's monthly wage pursuant to section 655.210(g)(2) must include the reason for the worker's absence. Such records will enable the employer, and the Department, if necessary, to determine whether the worker performed work on the range at least 50 percent of the days during the contract period.

In accordance with the PRA, 44 U.S.C. 3501, information collection requirements that must be implemented as a result of this regulation must receive approval from the Office of Management and Budget (OMB). Therefore, a clearance package containing the new requirements was submitted to OMB on April 15, 2015 as part of the proposed rule for the hiring of foreign workers in the H-2A program for herding or production of livestock on the open range in the United States under OMB Control Number 1205-0519. The public was given 60 days to comment on this information collection. OMB filed a comment asking the Department to resubmit the information collection at the final rule stage after considering public comments on the NPRM. The Department did resubmit the package prior to publication of this Final Rule. As of publication of this rule, OMB has not approved the information collection under OMB control number 1205-0519. No person is required to respond to a collection of information request unless the collection of the information has a valid OMB control number and expiration date. Therefore, until the Department publishes a **Federal Register** notice informing the public of the approval by OMB and the expiration date of the information collection, the affected parties do not have to comply with this information collection.

The Department received more than fifty comments about the new recordkeeping requirement as described in the NPRM. Forty seven of the comments opposed the new requirement and four supported the requirement. Many of those who opposed the new requirement misunderstood the requirement and thought that employers would need to keep hourly logs. In actuality, the logs only needed to reflect days on the range; and on those days when an employee worked on the ranch or farm, the employer needed to write down the number of hours worked and a description of the duties performed. The

duties did not need to be accounted for by hour and minutes. Those who agreed with the new requirement thought the burden was minimal.

However, in light of these and other comments, and as discussed above in Sec. IV.B.2.e. of the preamble related to § 655.210(f), the Department has decided to change this requirement in the Final Rule. Employers will now only be required to notate whether employees spend days on the ranch or on the range and the reason for any prorated salary paid.

This information collection in this Final Rule creates an associated paperwork burden on the employers that must be assessed under the PRA. Based on the average number of employers filing applications for H-2A workers to perform herding work filed with the Department in 2013 and 2014, the Department estimates that the information collection will affect 485 employers employing foreign shepherders, goat herders, and other workers engaged in the open range production of livestock. The Department further estimates that it will take each employer, on average, 5 minutes each week to prepare timesheets for its employees, and 1 minute each week to store these timesheets. Thus, the reporting burden for 485 employers is 2,425 minutes (485 employers × 5 minutes) per week, or approximately 40 hours per week. When annualized, the total reporting burden is 2,000 hours per year (40 hours per week × 50 weeks). The total record keeping burden for 485 employers is 485 minutes (485 employers × 1 minute) per week, or 8 hours per week. When annualized, the total recordkeeping burden is 400 hours per year (8 hours per week × 50 weeks). When these two sums are added together, the total employer reporting and recordkeeping burden is 2,400 hours per year.

When estimating the cost burden of paperwork requirements, the Department used the average salary of a Human Resources Manager based on the national cross-industry mean hourly wage rate for a Human Resources Manager (\$54.88), from the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics survey wage data,¹³⁷ and increased by a factor of 1.43 to account for employee benefits and other compensation, for a total hourly cost of \$78.48. This number was multiplied by the total hourly annual burden created

for this new requirement, which, as noted above, is 2,400 hours per year. The total annual respondent hourly costs for this new burden placed on the employers in the shepherding and open range production of livestock is estimated as follows:

Total burden cost of this provision is 2,400 hours × \$78.48 = \$188,352 per year. The total costs other than the time associated with the information collections required under this Final Rule, as defined by the PRA, are zero dollars per employer.

As noted above, this collection of information is subject to the PRA. Accordingly, this information collection in this Final Rule has been submitted to OMB for review under 44 U.S.C. 3507(d) of the PRA. For an additional explanation of how the Department calculated the burden hours and related costs, the PRA package for this information collection (OMB Control Number 1205-0519) can be obtained from the RegInfo.gov Web site at <http://www.reginfo.gov/public/dol/pramain> or by contacting the Department at Office of Policy Development and Research, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210 or by phone request to 202-693-3700 (this is not a toll-free number) or by email at DOL_PRA_PUBLIC@dol.gov.

Overview of the Information Collection

Type of Review: New Collection.

Agency: Employment and Training Administration.

Title: H-2A Shepherd Recordkeeping Requirement.

OMB Number: 1205-0519.

Affected Public: Farm businesses.

Form(s): None.

Total Annual Respondents: 485.

Annual Frequency: Weekly (50 weeks).

Total Annual Responses: 242,250.

Average Time per Response: 6 minutes.

Estimated Total Annual Burden

Hours: 2,400 hours per year.

Total Annual Start-up/Capital/Maintenance Costs for Respondents: \$0.

List of Subjects in 20 CFR Part 655

Administrative practice and procedure, Employment, Employment and training, Enforcement, Foreign workers, Forest and forest products, Fraud, Health professions, Immigration, Labor, Passports and visas, Penalties, Reporting and recordkeeping requirements, Unemployment, Wages, Working conditions.

For the reasons discussed in the preamble, the Department of Labor amends 20 CFR part 655 as follows:

¹³⁷ Source: Bureau of Labor Statistics, Occupational Employment Statistics; May 2014 National Occupational Employment and Wage Estimates; Management Occupations.

**PART 655—TEMPORARY
EMPLOYMENT OF FOREIGN
WORKERS IN THE UNITED STATES**

■ 1. Revise the general authority citation and the subpart B authority citation for part 655 to read as follows:

Authority: Section 655.0 issued under 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i) and (ii), 1182(m), (n) and (t), 1184(c), (g), and (j), 1188, and 1288(c) and (d); sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; sec. 412(e), Pub. L. 105–277, 112 Stat. 2681 (8 U.S.C. 1182 note); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109–423, 120 Stat. 2900; and 8 CFR 214.2(h)(4)(i).

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Subpart B issued under 8 U.S.C. 1101(a)(15)(H)(ii), 1184(c), and 1188; and 8 CFR 214.2(h).

* * * * *

■ 2. Subpart B is amended by adding the following undesignated center heading, and §§ 655.200, 655.201, 655.205, 655.210, 655.211, 655.215, 655.220, 655.225, 655.230, and 655.235 to read as follows:

**Labor Certification Process for
Temporary Agricultural Employment in
Range Sheep herding, Goat Herding,
and Production of Livestock
Occupations**

Sec.

655.200 Scope and purpose of herding and range livestock regulations.

655.201 Definition of herding and range livestock terms.

655.205 Herding and range livestock job orders.

655.210 Contents of herding and range livestock job orders.

655.211 Herding and range livestock wage rate.

655.215 Procedures for filing herding and range livestock applications for temporary employment certification.

655.220 Processing herding and range livestock applications for temporary employment certification.

655.225 Post-acceptance requirements for herding and range livestock.

655.230 Range housing.

655.235 Standards for range housing.

§ 655.200 Scope and purpose of herding and range livestock regulations.

(a) *Purpose.* The purpose of §§ 655.200–655.235 is to establish certain procedures for employers who apply to the Department of Labor to obtain labor certifications to hire temporary agricultural foreign workers to perform herding or production of livestock on the range, as defined in

§ 655.201. Unless otherwise specified in §§ 655.200–655.235, employers whose job opportunities meet the qualifying criteria under §§ 655.200–655.235 must fully comply with all of the requirements of §§ 655.100–655.185; part 653, subparts B and F; and part 654 of this chapter.

(b) *Jobs subject to §§ 655.200–655.235.* These procedures apply to job opportunities with the following unique characteristics:

(1) The work activities involve the herding or production of livestock (which includes work that is closely and directly related to herding and/or the production of livestock), as defined under § 655.201;

(2) The work is performed on the range for the majority (meaning more than 50 percent) of the workdays in the work contract period. Any additional work performed at a place other than the range must constitute the production of livestock (which includes work that is closely and directly related to herding and/or the production of livestock); and

(3) The work activities generally require the workers to be on call 24 hours per day, 7 days a week.

§ 655.201 Definition of herding and range livestock terms.

The following are terms that are not defined in §§ 655.100–655.185 and are specific to applications for labor certifications involving the herding or production of livestock on the range.

Herding. Activities associated with the caring, controlling, feeding, gathering, moving, tending, and sorting of livestock on the range.

Livestock. An animal species or species group such as sheep, cattle, goats, horses, or other domestic hooved animals. In the context of §§ 655.200–655.235, livestock refers to those species raised on the range.

Production of livestock. The care or husbandry of livestock throughout one or more seasons during the year, including guarding and protecting livestock from predatory animals and poisonous plants; feeding, fattening, and watering livestock; examining livestock to detect diseases, illnesses, or other injuries; administering medical care to sick or injured livestock; applying vaccinations and spraying insecticides on the range; and assisting with the breeding, birthing, raising, weaning, castration, branding, and general care of livestock. This term also includes duties performed off the range that are closely and directly related to herding and/or the production of livestock. The following are non-exclusive examples of ranch work that is closely and directly

related: repairing fences used to contain the herd; assembling lambing jugs; cleaning out lambing jugs; feeding and caring for the dogs that the workers use on the range to assist with herding or guarding the flock; feeding and caring for the horses that the workers use on the range to help with herding or to move the sheep camps and supplies; and loading animals into livestock trucks for movement to the range or to market. The following are examples of ranch work that is not closely and directly related: working at feedlots; planting, irrigating and harvesting crops; operating or repairing heavy equipment; constructing wells or dams; digging irrigation ditches; applying weed control; cutting trees or chopping wood; constructing or repairing the bunkhouse or other ranch buildings; and delivering supplies from the ranch to the herders on the range.

Range. The range is any area located away from the ranch headquarters used by the employer. The following factors are indicative of the range: it involves land that is uncultivated; it involves wide expanses of land, such as thousands of acres; it is located in a remote, isolated area; and typically range housing is required so that the herder can be in constant attendance to the herd. No one factor is controlling and the totality of the circumstances is considered in determining what should be considered range. The range does not include feedlots, corrals, or any area where the stock involved would be near ranch headquarters. Ranch headquarters, which is a place where the business of the ranch occurs and is often where the owner resides, is limited and does not embrace large acreage; it only includes the ranchhouse, barns, sheds, pen, bunkhouse, cookhouse, and other buildings in the vicinity. The range also does not include any area where a herder is not required to be available constantly to attend to the livestock and to perform tasks, including but not limited to, ensuring the livestock do not stray, protecting them from predators, and monitoring their health.

Range housing. Range housing is housing located on the range that meets the standards articulated under § 655.235.

§ 655.205 Herding and range livestock job orders.

The employer whose job opportunity has been determined to qualify for these procedures, whether individual, association, or H–2ALC, is not required to comply with the job order filing requirements in § 655.121(a) through (d). Rather, the employer must submit

Form ETA-790, directly to the National Processing Center (NPC) designated by the Office of Foreign Labor Certification (OFLC Administrator) along with a completed *H-2A Application for Temporary Employment Certification*, Form ETA-9142A, as required in § 655.215.

§ 655.210 Contents of job herding and range livestock orders.

(a) *Content of job offers.* Unless otherwise specified in §§ 655.200–655.235, the employer, whether individual, association, or H-2ALC, must satisfy the requirements for job orders established under § 655.121(e) and for the content of job offers established under part 653, subpart F of this chapter and § 655.122.

(b) *Job qualifications and requirements.* The job offer must include a statement that the workers are on call for up to 24 hours per day, 7 days per week and that the workers spend the majority (meaning more than 50 percent) of the workdays during the contract period in the herding or production of livestock on the range. Duties may include activities performed off the range only if such duties constitute the production of livestock (which includes work that is closely and directly related to herding and/or the production of livestock). All such duties must be specifically disclosed on the job order. The job offer may also specify that applicants must possess up to 6 months of experience in similar occupations involving the herding or production of livestock on the range and require reference(s) for the employer to verify applicant experience. An employer may specify other appropriate job qualifications and requirements for its job opportunity. Job offers may not impose on U.S. workers any restrictions or obligations that will not be imposed on the employer's H-2A workers engaged in herding or the production of livestock on the range. Any such requirements must be applied equally to both U.S. and foreign workers. Each job qualification and requirement listed in the job offer must be bona fide, and the Certifying Officer (CO) may require the employer to submit documentation to substantiate the appropriateness of any other job qualifications and requirements specified in the job offer.

(c) *Range housing.* The employer must specify in the job order that range housing will be provided. The range housing must meet the requirements set forth in § 655.235.

(d) *Employer-provided items.* (1) The employer must provide to the worker, without charge or deposit charge, all tools, supplies, and equipment required

by law, by the employer, or by the nature of the work to perform the duties assigned in the job offer safely and effectively. The employer must specify in the job order which items it will provide to the worker.

(2) Because of the unique nature of the herding or production of livestock on the range, this equipment must include effective means of communicating with persons capable of responding to the worker's needs in case of an emergency including, but not limited to, satellite phones, cell phones, wireless devices, radio transmitters, or other types of electronic communication systems. The employer must specify in the job order:

(i) The type(s) of electronic communication device(s) and that such device(s) will be provided without charge or deposit charge to the worker during the entire period of employment; and

(ii) If there are periods of time when the workers are stationed in locations where electronic communication devices may not operate effectively, the employer must specify in the job order, the means and frequency with which the employer plans to make contact with the workers to monitor the worker's well-being. This contact must include either arrangements for the workers to be located, on a regular basis, in geographic areas where the electronic communication devices operate effectively, or arrangements for regular, pre-scheduled, in-person visits between the workers and the employer, which may include visits between the workers and other persons designated by the employer to resupply the workers' camp.

(e) *Meals.* The employer must specify in the job offer and provide to the worker, without charge or deposit charge:

(1) Either three sufficient meals a day, or free and convenient cooking facilities and adequate provision of food to enable the worker to prepare his own meals. To be sufficient or adequate, the meals or food provided must include a daily source of protein, vitamins, and minerals; and

(2) Adequate potable water, or water that can be easily rendered potable and the means to do so. Standards governing the provision of water to range workers are also addressed in § 655.235(e).

(f) *Hours and earnings statements.* (1) The employer must keep accurate and adequate records with respect to the worker's earnings and furnish to the worker on or before each payday a statement of earnings. The employer is exempt from recording the hours actually worked each day, the time the

worker begins and ends each workday, as well as the nature and amount of work performed, but all other regulatory requirements in § 655.122(j) and (k) apply.

(2) The employer must keep daily records indicating whether the site of the employee's work was on the range or off the range. If the employer prorates a worker's wage pursuant to paragraph (g)(2) of this section because of the worker's voluntary absence for personal reasons, it must also keep a record of the reason for the worker's absence.

(g) *Rates of pay.* The employer must pay the worker at least the monthly AEW, as specified in § 655.211, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action, in effect at the time work is performed, whichever is highest, for every month of the job order period or portion thereof.

(1) The offered wage shall not be based on commissions, bonuses, or other incentives, unless the employer guarantees a wage that equals or exceeds the monthly AEW, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action, or any agreed-upon collective bargaining rate, whichever is highest, and must be paid to each worker free and clear without any unauthorized deductions.

(2) The employer may prorate the wage for the initial and final pay periods of the job order period if its pay period does not match the beginning or ending dates of the job order. The employer also may prorate the wage if an employee is voluntarily unavailable to work for personal reasons.

(h) *Frequency of pay.* The employer must state in the job offer the frequency with which the worker will be paid, which must be at least twice monthly. Employers must pay wages when due.

§ 655.211 Herding and range livestock wage rate.

(a) *Compliance with rates of pay.* (1) To comply with its obligation under § 655.210(g), an employer must offer, advertise in its recruitment and pay each worker employed under §§ 655.200–655.235 a wage that is the highest of the monthly AEW established under this section, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State law or judicial action.

(2) If the monthly AEW established under this section is adjusted during a work contract, and is higher than both the agreed-upon collective bargaining

wage and the applicable minimum wage imposed by Federal or State law or judicial action in effect at the time the work is performed, the employer must pay that adjusted monthly AEWR upon publication by the Department in the **Federal Register**.

(b) *Publication of the monthly AEWR.* The OFLC Administrator will publish a notice in the **Federal Register**, at least once in each calendar year, on a date to be determined by the OFLC Administrator, establishing the monthly AEWR.

(c) *Monthly AEWR Rate.* (1) The monthly AEWR shall be \$7.25 multiplied by 48 hours, and then multiplied by 4.333 weeks per month; and

(2) Beginning for calendar year 2017, the monthly AEWR shall be adjusted annually based on the Employment Cost Index for wages and salaries published by the Bureau of Labor Statistics (ECI) for the preceding October–October period.

(d) *Transition Rates.* (1) For the period from the effective date of this rule through calendar year 2016, the Department shall set the monthly AEWR at 80% of the result of the formula in paragraph (c) of this section.

(2) For calendar year 2017, the Department shall set the monthly AEWR at 90% of the result of the formula in paragraph (c) of this section.

(3) For calendar year 2018 and beyond, the Department shall set the monthly AEWR at 100% of the result of the formula in paragraph (c) of this section.

§ 655.215 Procedures for filing herding and range livestock applications for temporary employment certification.

(a) *Compliance with §§ 655.130–655.132.* Unless otherwise specified in §§ 655.200–655.235, the employer must satisfy the requirements for filing an *H–2A Application for Temporary Employment Certification* with the NPC designated by the OFLC Administrator as required under §§ 655.130–655.132.

(b) *What to file.* An employer must file a completed *H–2A Application for Temporary Employment Certification* (Form ETA–9142A), *Agricultural and Food Processing Clearance Order* (Form ETA–790), and an attachment identifying, with as much geographic specificity as possible for each farmer/rancher, the names, physical locations and estimated start and end dates of need where work will be performed under the job order.

(1) The *H–2A Application for Temporary Employment Certification* and Form ETA–790 may be filed by an individual employer, association, or an

H–2ALC, covering multiple areas of intended employment and more than two contiguous States.

(2) The period of need identified on the *H–2A Application for Temporary Employment Certification* and job order for range sheep or goat herding or production occupations must be no more than 364 calendar days. The period of need identified on the *H–2A Application for Temporary Employment Certification* and job order for range herding or production of cattle, horses, or other domestic hooved livestock, except sheep and goats, must be for no more than 10 months.

(3) An association of agricultural employers filing as a joint employer may submit a single Form ETA–790 and master *H–2A Application for Temporary Employment Certification* on behalf of its employer-members located in more than two contiguous States with different start dates of need. Unless modifications to a sheep or goat herding or production of livestock job order are required by the CO or requested by the employer, pursuant to § 655.121(e), the association is not required to re-submit the Form ETA–790 during the calendar year with its *H–2A Application for Temporary Employment Certification*.

§ 655.220 Processing herding and range livestock applications for temporary employment certification.

(a) *NPC Review.* Unless otherwise specified in §§ 655.200–655.235, the CO will review and process the *H–2A Application for Temporary Employment Certification* and the Form ETA–790 in accordance with the requirements outlined in §§ 655.140–655.145, and will work with the employer to address any deficiencies in the job order in a manner consistent with §§ 655.140–655.141.

(b) *Notice of acceptance.* Once the job order is determined to meet all regulatory requirements, the NPC will issue a Notice of Acceptance consistent with § 655.143(b)(1). The CO will provide notice to the employer authorizing conditional access to the interstate clearance system; identify and transmit a copy of the Form ETA–790 to any one of the SWAs having jurisdiction over the anticipated worksites, and direct the SWA to place the job order promptly in intrastate and interstate clearance (including all States where the work will take place); and commence recruitment of U.S. workers. Where an association of agricultural employers files as a joint employer and submits a single Form ETA–790 on behalf of its employer-members, the CO will transmit a copy of the Form ETA–790 to the SWA having jurisdiction over the

location of the association, again directing that SWA to place the job order in intrastate and interstate clearance, including to those other States where the work will take place, and commence recruitment of U.S. workers.

(c) *Electronic job registry.* Under § 655.144(b), where a single job order is approved for an association of agricultural employers filing as a joint employer on behalf of its employer-members with different start dates of need, the Department will keep the job order posted on the OFLC electronic job registry until 50 percent of the period of the work contract has elapsed for all employer-members identified on the job order.

§ 655.225 Post-acceptance requirements for herding and range livestock.

(a) Unless otherwise specified in this section, the requirements for recruiting U.S. workers by the employer and SWA must be satisfied, as specified in §§ 655.150–655.158.

(b) *Interstate clearance of job order.* Pursuant to § 655.150(b), where a single job order is approved for an association of agricultural employers filing as a joint employer on behalf of its employer-members with different start dates of need, each of the SWAs to which the Form ETA–790 was transmitted by the CO or the SWA having jurisdiction over the location of the association must keep the job order on its active file until 50 percent of the period of the work contract has elapsed for all employer-members identified on the job order, and must refer to the association each qualified U.S. worker who applies (or on whose behalf an application is made) for the job opportunity.

(c) Any eligible U.S. worker who applies (or on whose behalf an application is made) for the job opportunity and is hired will be placed at the location nearest to him/her absent a request for a different location by the U.S. worker. Employers must make reasonable efforts to accommodate such placement requests by the U.S. worker.

(d) The employer will not be required to place an advertisement in a newspaper of general circulation serving the area of intended employment, as required in § 655.151.

(e) An association that fulfills the recruitment requirements for its members is required to maintain a written recruitment report containing the information required by § 655.156 for each individual employer-member identified in the application or job order, including any approved modifications.

§ 655.230 Range housing.

(a) Housing for work performed on the range must meet the minimum standards contained in § 655.235 and § 655.122(d)(2).

(b) The SWA with jurisdiction over the location of the range housing must inspect and certify that such housing used on the range is sufficient to accommodate the number of certified workers and meets all applicable standards contained in § 655.235. The SWA must conduct a housing inspection no less frequently than once every three calendar years after the initial inspection and provide documentation to the employer certifying the housing for a period lasting no more than 36 months. If the SWA determines that an employer's housing cannot be inspected within a 3-year timeframe or, when it is inspected, the housing does not meet all the applicable standards, the CO may deny the H-2A application in full or in part or require additional inspections, to be carried out by the SWA, in order to satisfy the regulatory requirement.

(c)(1) The employer may self-certify its compliance with the standards contained in § 655.235 only when the employer has received a certification from the SWA for the range housing it seeks to use within the past 36 months.

(2) To self-certify the range housing, the employer must submit a copy of the valid SWA housing certification and a written statement, signed and dated by the employer, to the SWA and the CO assuring that the housing is available, sufficient to accommodate the number of workers being requested for temporary labor certification, and meets all the applicable standards for range housing contained in § 655.235.

(d) The use of range housing at a location other than the range, where fixed site employer-provided housing would otherwise be required, is permissible only when the worker occupying the housing is performing work that constitutes the production of livestock (which includes work that is closely and directly related to herding and/or the production of livestock). In such a situation, workers must be granted access to facilities, including but not limited to toilets and showers with hot and cold water under pressure, as well as cooking and cleaning facilities, that would satisfy the requirements contained in § 655.122(d)(1)(i). When such work does not constitute the production of livestock, workers must be housed in housing that meets all the requirements of § 655.122(d).

§ 655.235 Standards for range housing.

An employer employing workers under §§ 655.200–655.235 may use a mobile unit, camper, or other similar mobile housing vehicle, tents, and remotely located stationary structures along herding trails, which meet the following standards:

(a) *Housing site.* Range housing sites must be well drained and free from depressions where water may stagnate.

(b) *Water supply.* (1) An adequate and convenient supply of water that meets the standards of the state or local health authority must be provided.

(2) The employer must provide each worker at least 4.5 gallons of potable water, per day, for drinking and cooking, delivered on a regular basis, so that the workers will have at least this amount available for their use until this supply is next replenished.

Employers must also provide an additional amount of water sufficient to meet the laundry and bathing needs of each worker. This additional water may be non-potable, and an employer may require a worker to rely on natural sources of water for laundry and bathing needs if these sources are available and contain water that is clean and safe for these purposes. If an employer relies on alternate water sources to meet any of the workers' needs, it must take precautionary measures to protect the worker's health where these sources are also used to water the herd, dogs, or horses, to prevent contamination of the sources if they collect runoff from areas where these animals excrete.

(3) The water provided for use by the workers may not be used to water dogs, horses, or the herd.

(4) In situations where workers are located in areas that are not accessible by motorized vehicle, an employer may request a variance from the requirement that it deliver potable water to workers, provided the following conditions are satisfied:

(i) It seeks the variance at the time it submits its *H-2A Application for Temporary Employment Certification*, Form ETA-9142A;

(ii) It attests that it has identified natural sources of water that are potable or may be easily rendered potable in the area in which the housing will be located, and that these sources will remain available during the period the worker is at that location;

(iii) It attests that it shall provide each worker an effective means to test whether the water is potable and, if not potable, the means to easily render it potable; and

(iv) The CO approves the variance.

(5) Individual drinking cups must be provided; and

(6) Containers appropriate for storing and using potable water must be provided and, in locations subject to freezing temperatures, containers must be small enough to allow storage in the housing unit to prevent freezing.

(c) *Excreta and liquid waste disposal.*

(1) Facilities, including shovels, must be provided and maintained for effective disposal of excreta and liquid waste in accordance with the requirements of the state health authority or involved Federal agency; and

(2) If pits are used for disposal by burying of excreta and liquid waste, they must be kept fly-tight when not filled in completely after each use. The maintenance of disposal pits must be in accordance with state and local health and sanitation requirements.

(d) *Housing structure.* (1) Housing must be structurally sound, in good repair, in a sanitary condition and must provide shelter against the elements to occupants;

(2) Housing, other than tents, must have flooring constructed of rigid materials easy to clean and so located as to prevent ground and surface water from entering;

(3) Each housing unit must have at least one window that can be opened or skylight opening directly to the outdoors; and

(4) Tents appropriate to weather conditions may be used only where the terrain and/or land use regulations do not permit the use of other more substantial housing.

(e) *Heating.* (1) Where the climate in which the housing will be used is such that the safety and health of a worker requires heated living quarters, all such quarters must have properly installed operable heating equipment that supplies adequate heat. Where the climate in which the housing will be used is mild and the low temperature for any day in which the housing will be used is not reasonably expected to drop below 50 degrees Fahrenheit, no separate heating equipment is required as long as proper protective clothing and bedding are made available, free of charge or deposit charge, to the workers.

(2) Any stoves or other sources of heat using combustible fuel must be installed and vented in such a manner as to prevent fire hazards and a dangerous concentration of gases. If a solid or liquid fuel stove is used in a room with wooden or other combustible flooring, there must be a concrete slab, insulated metal sheet, or other fireproof material on the floor under each stove, extending at least 18 inches beyond the perimeter of the base of the stove.

(3) Any wall or ceiling within 18 inches of a solid or liquid fuel stove or

stove pipe must be made of fireproof material. A vented metal collar must be installed around a stovepipe or vent passing through a wall, ceiling, floor or roof.

(4) When a heating system has automatic controls, the controls must be of the type that cuts off the fuel supply when the flame fails or is interrupted or whenever a predetermined safe temperature or pressure is exceeded.

(5) A heater may be used in a tent if the heater is approved by a testing service and if the tent is fireproof.

(f) *Lighting.* (1) In areas where it is not feasible to provide electrical service to range housing units, including tents, lanterns must be provided (kerosene wick lights meet the definition of lantern); and

(2) Lanterns, where used, must be provided in a minimum ratio of one per occupant of each unit, including tents.

(g) *Bathing, laundry, and hand washing.* Bathing, laundry and hand washing facilities must be provided when it is not feasible to provide hot and cold water under pressure.

(h) *Food storage.* When mechanical refrigeration of food is not feasible, the worker must be provided with another means of keeping food fresh and preventing spoilage, such as a butane or propane gas refrigerator. Other proven methods of safeguarding fresh foods, such as dehydrating or salting, are acceptable.

(i) *Cooking and eating facilities.* (1) When workers or their families are permitted or required to cook in their individual unit, a space must be

provided with adequate lighting and ventilation; and

(2) Wall surfaces next to all food preparation and cooking areas must be of nonabsorbent, easy to clean material. Wall surfaces next to cooking areas must be made of fire-resistant material.

(j) *Garbage and other refuse.* (1) Durable, fly-tight, clean containers must be provided to each housing unit, including tents, for storing garbage and other refuse; and

(2) Provision must be made for collecting or burying refuse, which includes garbage, at least twice a week or more often if necessary, except where the terrain in which the housing is located cannot be accessed by motor vehicle and the refuse cannot be buried, in which case the employer must provide appropriate receptacles for storing the refuse and for removing the trash when the employer next transports supplies to the location.

(k) *Insect and rodent control.* Appropriate materials, including sprays, and sealed containers for storing food, must be provided to aid housing occupants in combating insects, rodents and other vermin.

(l) *Sleeping facilities.* A separate comfortable and clean bed, cot, or bunk, with a clean mattress, must be provided for each person, except in a family arrangement, unless a variance is requested from and granted by the CO. When filing an application for certification and only where it is demonstrated to the CO that it is impractical to provide a comfortable and clean bed, cot, or bunk, with a clean mattress, for each range worker, the

employer may request a variance from this requirement to allow for a second worker to join the range operation. Such a variance must be used infrequently, and the period of the variance will be temporary, *i.e.*, the variance shall be for no more than 3 consecutive days. Should the CO grant the variance, the employer must supply a sleeping bag or bed roll for the second occupant free of charge or deposit charge.

(m) *Fire, safety, and first aid.* (1) All units in which people sleep or eat must be constructed and maintained according to applicable state or local fire and safety law.

(2) No flammable or volatile liquid or materials may be stored in or next to rooms used for living purposes, except for those needed for current household use.

(3) Housing units for range use must have a second means of escape through which the worker can exit the unit without difficulty.

(4) Tents are not required to have a second means of escape, except when large tents with walls of rigid material are used.

(5) Adequate, accessible fire extinguishers in good working condition and first aid kits must be provided in the range housing.

Signed in Washington this 9th day of October, 2015.

Portia Wu,

Assistant Secretary, Employment and Training Administration.

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